

1362463

# THE UNITED STATES OF AMERICA

TO ALL TO WHOM THESE PRESENTS SHALL COME:

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

*August 29, 2005*

THIS IS TO CERTIFY THAT ANNEXED HERETO IS A TRUE COPY FROM THE RECORDS OF THE UNITED STATES PATENT AND TRADEMARK OFFICE OF THOSE PAPERS OF THE BELOW IDENTIFIED PATENT APPLICATION THAT MET THE REQUIREMENTS TO BE GRANTED A FILING DATE.

APPLICATION NUMBER: 60/589,524

FILING DATE: *July 20, 2004*

RELATED PCT APPLICATION NUMBER: PCT/US05/25633



Certified by

Under Secretary of Commerce  
for Intellectual Property  
and Director of the United States  
Patent and Trademark Office

# PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).

Express Mail Label No. **ER 281676956 US**

## INVENTOR(S)

Given Name (first and middle (if any))

**JASON  
PAUL**

Family Name or Surname

**AUGUST  
WATERHOUSE**

Residence  
(City and either State or Foreign Country)

**TORONTO, CANADA  
COPETOWN, ONTARIO,  
CANADA**

☒ Additional inventors are being named on the 1 separately numbered sheets attached hereto

## TITLE OF THE INVENTION (500 characters max)

**RF-ENABLEMENT OF PRODUCTS AND  
RECEPTACLES THEREFOR**

Direct all correspondence to:

## CORRESPONDENCE ADDRESS

☐ Customer Number

OR

☐ Firm or  
Individual Name

Type Customer Number here

Place Customer Number  
Bar Code Label here

**JASON AUGUST**

Address

**240 SUTHERLAND DRIVE**

Address

City

**TORONTO**

State

**ONTARIO**

ZIP

**M4G 1J3**

Country

**CANADA**

Telephone

**416-696-5119**

Fax

**203-698-1025**

## ENCLOSED APPLICATION PARTS (check all that apply)

☒ Specification Number of Pages

**22**

☒ Drawing(s) Number of Sheets

**66**

☐ CD(s), Number

☐ Other (specify)

☐ Application Data Sheet. See 37 CFR 1.76

## METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☒ Applicant claims small entity status. See 37 CFR 1.27.

☒ A check or money order is enclosed to cover the filing fees

☐ The Commissioner is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number:

☐ Payment by credit card. Form PTO-2038 is attached.

FILING FEE  
AMOUNT (\$)

**80.00**

The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☐ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are:

Respectfully submitted

SIGNATURE

Date

**7/20/2004**

TYPED or PRINTED NAME

**JASON AUGUST**

REGISTRATION NO.  
(if appropriate)

Docket Number:

TELEPHONE

**416-723-2008**

**SmartPak**

## USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT

This collection of information is required by 37 CFR 1.51. The information is used by the public to file (and by the PTO to process) a provisional application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 8 hours to complete, including gathering, preparing, and submitting the complete provisional application to the PTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, D.C. 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Box Provisional Application, Assistant Commissioner for Patents, Washington, D.C. 20231.

**PROVISIONAL APPLICATION COVER SHEET**  
Additional Page

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

Approved for use through 10/31/2002. OMB 0851-0032  
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

PTO/SB/18 (10-01)

Docket Number

Smart Pak

**INVENTOR(S)/APPLICANT(S)**

Given Name (first and middle (if any))

Family or Surname

Residence  
(City and either State or Foreign Country)

JOHN K.

STEVENS

STRATHAM, NEW HAMPSHIRE

Number 2 of 2

**WARNING:** Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.



22763 U.S. PTO

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Stevens et al

Serial no. : To be assigned

Group no. :

Filed: Herewith

Examiner;

For: RF-ENABLEMENT OF PRODUCTS AND RECEPTACLES THEREFOR

Commissioner of Patents and Trademarks,  
Washington, D.C. 20231

EXPRESS MAIL CERTIFICATE

"Express Mail" label number ER 281676956 US

Date of Deposit July 20, 2004

I hereby certify that the attached paper or fee:

provisional patent application 22 pages (spec, claims, abstract)


provisional patent application cover sheet

55 ~~56~~ sheets of informal drawings

check for \$80.00

return post card

are being deposited with the United States Postal service "Express Mail post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to: Mail Stop  
Provisional Application, Commissioner for Patents, P.O. Box 1450, Alexandria,  
VA, 22313-1450

  
C.P. August



## **RF-ENABLEMENT OF PRODUCTS AND RECEPTACLES THEREFOR**

### **FIELD OF THE INVENTION**

This invention relates to identification and tracking of products, receptacles (including containers, boxes, and pallets), and other objects as they are transported and stored in moving through the supply chain from manufacturer to end-user. More particularly, the invention relates to the use of RFID tags and antennas therefor in receptacles, products, methods, and systems to achieve full visibility of products throughout the levels of their supply chain.

### **BACKGROUND OF THE INVENTION**

High-value products such as medical devices must often be tracked traced and details recorded as it moves through a supply chain. In many cases the medical device itself is temperature sensitive, and time sensitive, and may have a specific expiry date. Many of these medical devices may be worth thousands to even tens of thousands of dollars. Therefore, security tracking and optimized inventory may be not only critical to the business but also could provide audit trial information that may be required by governmental authorities, such as the FDA (the United States Food and Drug Administration ).

Many have proposed or discussed the use of radio frequency tags or what is now known as RF ID to track these high-value assets through a supply chain (e.g. US5774876, US5804810). In most cases these RF tags are placed either inside the box containing

the asset, or placed outside the box using an adhesive tape or other attachment means. These tags are read by a mobile reader or in some cases by a fixed reader to identify the product. Moreover, smart radio tags can use features such as a Liquid Crystal Display (LCD) to indicate status of the asset; temperature sensors to provide data logs and alarms if certain temperature parameters are not met; light emitting diodes or LEDs as indicators to make picking and putting the asset optimal; and buttons and that may be used to detect whether the tag is attached too a package or enabling human input to the tag. These tags may typically be the size of the credit card or slightly larger. However several serious problems arise when tracking high-value assets that require full pedigree audits and reliable proof that the medical device (e.g. stent) or other product has not been tampered with, as well as to provide many other options.

## SUMMARY OF THE INVENTION

Broadly and generally, the present invention provides integration of either entire RFID tags or only antennas thereof into objects, such as products (e.g. medical stents, CD's (compact discs), prescription medicine bottles) and receptacles (e.g. containers, packages, boxes, ULD's (unit load devices, as used in air freight), warehouse shelving, and the like) used to hold products.

Accordingly, the present invention provides an object operable for communicating wireless radio frequency (RF) signals, the aforesaid object comprising an antenna integrated (for example, an embedded ferrite loop) therewith.

Preferably, the aforesaid integrated antenna may be embedded into the aforesaid object (e.g. a CD/compact disk; a ULD (Unit Load Device), meat tray or other receptacle).

Moreover, the aforesaid integrated antenna should preferably have a dimension thereof that is substantially as large as a dimension of said object. The use of large antennas is particularly advantageous for low RF signal frequencies not exceeding 15 megahertz, and preferably not exceeding 1 megahertz. Moreover, the aforesaid integrated antenna may preferably comprise a loop integrated into the aforesaid object in each of two substantially orthogonal dimensions thereof.

According to a preferred embodiment, the aforesaid object comprises a product (e.g. stent) and an RFID tag attached thereto (e.g. integrated therewith), the aforesaid RFID tag comprising a transmitter and a tag antenna (preferably much smaller than the integrated antenna) operable to transmit wireless RF signals to the aforesaid integrated antenna.

Preferably, the aforesaid RFID tag is passive and further comprises a receiver, a microprocessor, a data storage device operable to store a selected code (e.g. an ID code to identify said object or said product), the aforesaid tag antenna being operable to receive incoming wireless RF signals from the integrated antenna and to communicate them to the receiver, the receiver being operable to communicate them to the microprocessor, the microprocessor being operable to read the aforesaid selected code (e.g. the aforesaid ID code) from the aforesaid data storage device in response to a selected set of said incoming wireless RF signals and to transmit such selected code wirelessly from the tag antenna to the integrated antenna, the integrated antenna being operable thereupon to transmit the aforesaid ID code wirelessly to a field antenna, which can communicate with the directly or by satellite to a central station or the internet.

According to another preferred embodiment, the aforesaid object comprises a receptacle and an RFID tag attached thereto (e.g. integrated therewith), the aforesaid RFID tag comprising a transmitter and a tag antenna operable to transmit wireless RF signals to the aforesaid integrated antenna.

According to another preferred embodiment, the aforesaid RFID tag is active and further comprises a microprocessor, a data storage device operable to store a selected code (e.g. an ID code to identify said object or said product), the aforesaid object comprising a display for displaying the aforesaid selected code upon a signal from the aforesaid microprocessor and an energy storage device (e.g. a lithium ion battery), operable to energize the microprocessor, the display, and the transmitter.

Preferably, the aforesaid receptacle is operable to hold a product, the receptacle comprising a sensor operable to generate a signal characteristic of a condition (e.g. temperature, jog, etc.) experienced by the aforesaid product.

Thus, the aforesaid object may comprise a receptacle (e.g. a tray for holding meat), such receptacle being operable to receive and hold a product (e.g. a steak, a stent), such product having an RFID tag attached thereto and being operable for communicating the wireless radio signals (e.g. of a frequency not exceeding 1 MHZ ) between said product and the aforesaid integrated antenna in the aforesaid receptacle.

The invention also provides a receptacle comprising:

a body portion operable to hold a product,

an RFID tag attached to the aforesaid body portion, the aforesaid RFID tag comprising a receiver, a transmitter, and an antenna, the aforesaid antenna being integrated into a unitary relationship with the aforesaid body portion.

Preferably, the aforesaid RFID tag is operable to receive and transmit wirelessly at a frequency not exceeding 15 megahertz, with even lower frequencies not exceeding 1 megahertz, and even 300 kilohertz) being especially desirable for greater signal strength.

Preferably, the aforesaid antenna comprises a loop antenna designed for superior strength of signal reception by having dimensions thereof scaled to dimensions of said body portion, and has a dimension thereof that is substantially as large as to a maximum

dimension of said receptacle. Moreover, the loop antenna preferably comprises a loop integrated into the aforesaid receptacle in each of two substantially orthogonal dimensions thereof.

Preferably, the aforesaid receptacle comprises a container operable to enclose the aforesaid product, such container further comprising a sensor disposed on a surface of the container and operable to generate a sealing signal indicating sealing of such container upon shrink-wrapping thereof.

Moreover, the aforesaid receptacle may comprise a container operable to enclose the aforesaid product, the aforesaid RFID tag further comprising a sensor disposed within such container and operable to generate a signal characteristic of a condition experienced by the product (e.g. temperature, light exposure, weight, humidity, and shock impulse (jog)). Preferably, the aforesaid RFID tag further comprising an indicator element for indicating impending expiry of viability of said product, as by providing a signal selected from visible light and audible sound. Such indicator element may comprise colored LED's, a blinking lamp, or an LCD display

Preferably, the aforesaid receptacle comprising a stackable container which is adapted for stacking upon other stackable containers to expose a surface of said stackable container for visual inspection, such stackable container further comprising an indicator element disposed on said surface and operable for indicating a condition selected from a) temperature of said product, b) sealing of said receptacle, c) light exposure within said stackable container, d) weight of said product, e) humidity within said stackable container, f) jog/shock imposed on said container, and g) impending expiry of viability of said product.

According to a preferred embodiment, the aforesaid receptacle may comprise a pallet, ULD, warehouse shelving unit operable to hold a plurality of containers with integrated antennas or entire RFID tags, each antenna having a dimension thereof that is

substantially as large as a maximum dimension of such pallet, ULD, or warehouse shelving unit.

The invention also provides a method of tracking the conditions of products, each such condition being selected from temperature, product enclosure (shrink-wrapping), light level, product weight, humidity, jog, product age/expiry, and product location (GPS coordinates), the aforesaid method comprising the steps of :

- a) placing each product onto a first receptacle, such first receptacle being provided with a sensor for an aforesaid condition and a passive RFID tag operable to emit first wireless signals that indicate a such condition of said product,
- b) placing the aforesaid first receptacle into a second receptacle, such second receptacle being provided with a sensor for a such condition and an active RFID tag operable to receive such first signals and to emit second signals, at a wireless frequency not exceeding 15 megahertz, that indicate an aforesaid condition of a first or second receptacle,
- c) detecting signals selected from the aforesaid first signals and the aforesaid second signals.

The aforesaid method may further comprise the step of :

- e) providing a visual or audible indication of a said condition.

Moreover, the aforesaid first receptacle may comprise a first antenna integrated therewith. Also, the aforesaid second receptacle may comprising a second antenna integrated therewith.

The invention further provides a method of tracking the conditions of products, each such condition being selected from temperature, product enclosure (shrink-wrapping), light level, product weight, humidity, jog, product age/expiry, and product location (GPS coordinates), the aforesaid method comprising the steps of :

- a) integrating a passive RFID tag with a product, such passive RFID tag comprising a product antenna integrated into the product, such passive RFID tag being operable to emit wireless RF identification (ID) signals operable to identify the aforesaid product in response to a wireless RF interrogation signal;
- b) placing the aforesaid product onto a first receptacle, such first receptacle being provided with a sensor for a said condition and an active RFID tag operable to emit the aforesaid RF interrogation signal, to receive the aforesaid ID signals, and to emit first RF signals operable to identify the aforesaid product and to indicate an aforesaid condition at the aforesaid first receptacle,
- c) placing the aforesaid first receptacle into a second receptacle, the aforesaid second receptacle being provided with a sensor for an aforesaid condition and an active RFID tag operable to receive the aforesaid first signals and to emit second RF signals that indicate an aforesaid condition at one of the aforesaid first and second receptacles,
- d) detecting auditable signals selected from the aforesaid first RF signals and the aforesaid second RF signals
- e) transmitting auditable signals (e.g. by cable or by high frequency RF) detected at step (d) to a central station for auditable recording thereat (e.g. on a write-once-only CD ).

This method may preferably further comprise the step of :

- e) providing a visual (e.g. on an LCD display) or audible (e.g. an alarm bell) indication of a the aforesaid condition.

Preferably, the first receptacle comprises a first antenna integrated therewith. Also, The aforesaid second receptacle comprising a second antenna integrated therewith.

Preferably, the aforesaid first and second RF signals have a frequency not exceeding 1 megahertz.

The invention further broadly provides a system of tracking the conditions of products, each said condition being selected from temperature, product enclosure (shrink-

wrapping), light level, product weight, humidity, jog, product age/expiry, and product location (GPS coordinates), the aforesaid system comprising:

- a) a passive RFID tag integrated with an aforesaid product, such passive RFID tag comprising a product antenna integrated into said product, such passive RFID tag being operable to emit wireless RF identification (ID) signals operable to identify the aforesaid product in response to a wireless RF interrogation signal;
- b) a first receptacle operable to hold the aforesaid product, the aforesaid first receptacle being provided with a sensor for a said condition and an active RFID tag operable to emit the aforesaid RF interrogation signal, to receive the aforesaid ID signals, and to emit first RF signals operable to identify the aforesaid product and to indicate an aforesaid condition at the aforesaid first receptacle,
- c) a second receptacle operable to hold the aforesaid first receptacle, the aforesaid second receptacle being provided with a sensor for an aforesaid condition and an active RFID tag operable to receive the aforesaid first signals and to emit second RF signals that indicate an aforesaid condition at one of the aforesaid first and second receptacles,
- d) a field antenna operable to detect auditable signals selected from the aforesaid first RF signals and aforesaid second RF signals
- e) a transmitter operable to transmit auditable signals (e.g. by cable or by high frequency RF) detected at step (d) to a central station (e.g. via a satellite) for auditable recording thereat (e.g. on a write-once-only CD ).

The aforesaid system may further comprise:

- e) an indicator operable to providing a visual (e.g. on an LCD display) or audible (e.g. an alarm bell) indication of an aforesaid condition.

Preferably, the aforesaid first receptacle comprises a first antenna integrated therewith. Also, the aforesaid second receptacle comprises a second antenna integrated therewith.



Preferably, the aforesaid first receptacle comprises a stackable box, the aforesaid second receptacle being selected from a pallet, a ULD Unit Load Device), and a warehouse shelving unit.

## DESCRIPTION OF THE DRAWINGS

FIG 1 is a schematic view of a novel receptacle (a Smart Package ) with an integrated antenna and RFID tag, in accordance with the present invention.

FIG 2 is a schematic view of a novel receptacle with an integrated antenna and active RFID tag and of a novel product (packaged stent) with an integrated antenna and a passive RFID tag.

FIG 3 is a schematic view of a novel receptacle with sensors therein.

FIG 4 is a schematic view of a novel receptacle in the form of a tote with an integrated antenna and active tag and of a number of smaller receptacles in the form of product containers with active tags integrated therein.

FIG 5 is a schematic view of a novel receptacle in the form of a pallet with an integrated antenna and active tag and of a number of smaller receptacles in the form of product containers with active tags integrated therein.

FIG 6 is a schematic view of a novel receptacle in the form of a tote with an integrated antenna and active tag and of a number of smaller receptacles in the form of pill bottles with passive tags integrated therein.

FIG 7 is a schematic view of a warehouse with a number of RF-enabled receptacles, in the form of boxes having RFID tags integrated therewith, a field antenna for 2-way

communication with the boxes, and a warehouse base station and server connected to the loop antenna.

FIG 8 is a schematic view of a warehouse with a number of RF-enabled receptacles, in the form of freight totes having RFID tags and antennas integrated therewith, a field antenna for 2-way communication with the boxes, and a warehouse server connected to the loop antenna.

FIG 9 is a schematic block diagram of RF-enablement components for use with a product or receptacle.

FIG 10 is a schematic view of an RF-enabled receptacle, showing the data stored therein, and a remote ASP server and connected Read-Only (write-once-only) CD recorder to create an audit trail shown by the data recorded therein.

FIG 11a is schematic plan view of a CD (compact disc) as a RF-enabled product.

FIG 11b is a cross-section along A-A of the CD shown in FIG 11a.

FIG 12a is schematic plan view of a meat tray as a RF-enabled receptacle.

FIG 11b is a cross-section along A-A of the meat tray shown in FIG 11a.

FIGS PPT 1-22 are presentation and text of a planned presentation relating, in part, to RF-enabled objects (products and receptacles) and systems and methods therefore, in accordance with the present invention.

## DESCRIPTION OF THE PREFERRED EMBODIMENTS

According to an embodiment of the present invention, the RFID tag is integrated into, and forms part of the receptacle ( e.g. container, package, tote, pallet) itself---- to make the package the tag and the tag the package. In one preferred embodiment the package would be a injection molded two-piece plastic box (with a top and a bottom), with electronics display and light emitting diodes (LED's) on the front of the plastic box. The inside of the box may have a light sensor/detector connected to the processor to indicate that it has not been opened as well as to provide history when the box was opened and closed during manufacturing. Optional buttons might be placed on the front of the package, so that when it becomes shrank wrapped with a plastic vacuum bag the buttons are depressed. Again, this provides a record of when the receptacle/package was sealed as well as when it was opened and thus an indication that the medical device (e.g. stent) package has not been tampered with until it goes into the patient. The display on the front of the package can be an alphanumeric display (e.g. LCD or liquid crystal display) and can be used to indicate the lot number, expiry dates, or any other critical information about the product held by the receptacle that might be useful to an end-user or to a person working in the warehouse. The LEDs could be used to indicate the product is expired and should not be used; alternatively, the LED indicators could also be flashed to indicate that this package is the next one to use when placed in a stack on a shelf. Other parameters such as temperature, jog history, humidity, can also be recorded and display on the LCD.

A great advantage of placing the electronics within the receptacle or package itself is the fact that the antenna or antennas can be larger and can be placed at different orientations on the receptacle, thereby increasing the strength of signal detected by the antenna, especially for lower frequencies of detected RF signal. According to the present invention, low frequencies not exceeding 15 megahertz, and advantageously not exceeding 1 megahertz, are preferred for use with such larger integrated antennas . In the case of a box receptacle, for example, loops of the antenna may be integrated, as by embedding into, the top, a side, and/or the back of the box, and thus a much larger area may be used for the antenna as compared to a conventional stick-on RFID tag or credit card size tag.

Advantageously, such a large antenna, which can be integrated into the receptacle in multiple orientations, can either a) be part of an RFID tag that is integrated into an object (a product or a receptacle for holding products) or (b) be a separate signal enhancement antenna (e.g. a ferrite loop) which can communicate at a close distance with a separate antenna of an RFID tag that is attached or integrated into the object.

As will be understood, there are many have unexpected advantages of incorporating an RFID tag or an antenna with an object (either a product such as a CD, or a receptacle/package itself, making a design which is more functional and at lower cost. In most cases these high-value assets are distributed within a "closed loop" supply chain—a supply chain that is controlled by a single entity, thereby enabling recycling of receptacles or boxes which are integrated with a large separate antenna or with a complete RFID tag. The ability to recycle receptacles/boxes, that have embedded RFID tags which store data (in a memory or data storage device) about the history of the receptacle and the conditions it has experienced, is also advantageous since the recycled receptacles can be used as proof of use and for settlement purposes. It would be possible to include in the memory (data storage device) of the box the full pedigree of history of the product's use from the date of its manufacture to the name and address of of delivery to the final customer/enduser (e.g. hospital patient)..

FIG 1 shows a typical RF-enabled receptacle 2, in the form of a Smart package/box, with an antenna 3 embedded into at least one side of container 2, a (LCD) liquid crystal display 5, two light emitting diodes 6, three buttons 7, and optional temperature and humidity sensors/detectors 8, as well as a light sensor/detector 8 placed inside of the box 2. The buttons 7 could be used to indicate that the item has been moved or opened or other purposes requiring human input. The buttons 7 also can be designed so that when the box 2 is shrink-wrapped with plastic film, the buttons 7 are compressed, thereby

providing a recordable indication that the package 2 is sealed, which can be used to prove that no one has tampered with this package 2.

FIG 2 is a schematic diagram for a RF-enabled box 2 and an RF-enabled product 1 (e.g. a bagged stent), with its own integrated antenna 3a and integrated passive RFID tag 4a. This box 2 and its tag 4a is similar to other radio frequency tags; however the printed circuit board and component parts shown in FIG 9 would be embedded into the plastic case portion for the box 2. The detector is might be placed inside of the box, and the loop antenna 3b shown in the block diagram may be placed on the top bottom or side of the box. It is also possible to place the loop antenna 3b on all three sides of the box to provide for enhanced and angle resistant communication. One of the major advantages of a RF-enabled product 1, package 2, or other object, over a more standard RFID tag is that the antennas 3a, 3b can be much larger, and antenna 3b can be in all three axes. A second advantage of a RF-enabled box/package 2 over a tag affixed to the exterior of a box is that sensors 8 may be selectively placed both inside the box 2 and outside the box 2. Moreover, an active RFID tag 4b can be used to interrogate the passive responder tags 4a that are integrated into the products 1 that are held in box 2.

FIG 3 shows that another advantage of an RF-enabled ("smart") box 2 over a standard tag is that the layout and positioning of the LCD display 5 and LED's 6 can be optimally configured for storage on a shelf. The boxes 2 may be stout and stackable vertically or another cases horizontally, and the form factor for thick boxes versus thin boxes etc. may be taken into account. Displays 5, buttons 7 and LED's 6 may be placed in the appropriate place for optimal storage and optimal use depending upon the product to be stored in totes 2 on shelving racks in a warehouse. It is possible to place a field loop antenna (see antenna 9 in FIGS 7 and 8) around a set of boxes 2 and communicate wirelessly to all smart boxes contained in such a field loop 9. This enables full product audits, inventory tracking, checks of status (i.e. has the box been opened and is-it/has-it-always-been at the correct temperature etc.) with no human intervention. This makes it possible to generate a full product pedigree while products are stored in such RF-enabled boxes 2 either directly on a data storage device of the RFID tag integrated into

the smart box 2 or the data received by antenna 9 may be stored on a local write-once-only CD or (via a warehouse web server 11 satellite and the internet) on a remote write-once-only CD.

FIG 4 and FIG 5 show that a number of RF-enabled boxes 2a (with integrated antennas 3a, tags 4a, LCD displays 5a, LED's 6a, and buttons 7a ) can be placed in/on a larger RF-enabled tote or pallet 2b which can be sealed and placed in the back of a truck equipped with a field antenna system 9 similar to that the described in FIGS 7, 8. All boxes 2a could then be checked by interrogation from tags 4b of totes/pallets 2b and confirmed while being transported, with GPS locations provided along with current temperature, time as depicted by data logs in FIG 10. These data logs would become part of the full product pedigree, and stored both in the smart box 2 as well as on a CD 17 connected to an ASP 16.

FIG 11a is schematic plan view of a CD (compact disc) as a RF-enabled product<sup>1</sup> with an integrated antenna 3 and RFID tag 4 embedded therein, while FIG 11b is a cross-section along A-A of the CD shown in FIG 11a.

FIG 12a is schematic plan view of a meat tray 2 as a RF-enabled receptacle with a large embedded antenna 3 (substantially as large as the two largest dimensions of tray 2 ) and an embedded RFID tag 4, which can alternatively be attached directly to product. 1 (a beef steak) . FIG 11b is a cross-section along A-A of the meat tray shown in FIG 11a.

FIGS PPT 1-22 and particularly FIGS PPT 6-22 explain and depict the operation and advantages of the inventive method, system, and of RF-enabled objects (products and receptacles).

While the present invention has been described with reference to preferred embodiments thereof, numerous obvious changes and variations may readily be made by persons skilled in the fields of asset tracking and RFID tags. Accordingly, the invention should be understood to include all such variations to the full extent embraced by the claims.

## WHAT IS CLAIMED IS:

A1. An object operable for communicating wireless radio frequency (RF) signals, said object comprising an antenna integrated (for example, embedded) therewith.

A2. An object as set forth in Claim A1, said integrated antenna being embedded into said object (e.g. a CD/compact disk; a ULD (Unit Load Device), meat tray or other receptacle).

A3. An object as set forth in Claim A1, said integrated antenna having a dimension thereof that is substantially as large as a dimension of said object.

A4. An object as set forth in Claim A1, said RF signals having a frequency not exceeding 15 megahertz.

A5. An object as set forth in Claim A1, said object comprising a product (e.g. stent) and an RFID tag attached thereto (e.g. integrated therewith), said RFID tag comprising a transmitter and a (preferably much smaller than the integrated antenna) tag antenna operable to transmit wireless RF signals to said integrated antenna.

A6. An object as set forth in Claim A1, said object comprising a receptacle and an RFID tag attached thereto (e.g. integrated therewith), said RFID tag comprising a transmitter and a (smaller) tag antenna operable to transmit wireless RF signals to said integrated antenna.

A7. An object as set forth in Claim A5, said RFID tag being passive and further comprising a receiver, a microprocessor, a data storage device operable to store a selected code (e.g. an ID code to identify said object or said product), said tag antenna being operable to receive incoming wireless RF signals from said integrated antenna and

to communicate them to said receiver, said receiver being operable to communicate them to said microprocessor, said microprocessor being operable to read said selected code (e.g. said ID code) from said data storage device in response to a selected set of said incoming wireless RF signals and to transmit said selected code wirelessly from said tag antenna to said integrated antenna, said integrated antenna being operable thereupon to transmit said ID code wirelessly to a field antenna.

A8. An object as set forth in Claim A5, said RFID tag being active and further comprising a microprocessor, a data storage device operable to store a selected code (e.g. an ID code to identify said object or said product), said object comprising a display for displaying said selected code upon a signal from said microprocessor and an energy storage device (e.g. a lithium ion battery, operable to energize said microprocessor, said display, and said transmitter.

A9. An object as set forth in Claim A6, said receptacle being operable to hold a product. said receptacle comprising a sensor operable to generate a signal characteristic of a condition (e.g. temperature, jog, etc.) experienced by said product.

A10. An object as set forth in Claim A1, said object comprising an RFID tag embedded therein.

A11. An object as set forth in Claim A4, wherein said embedded antenna comprises a ferrite loop.

A12. An object as set forth in Claim A1, wherein said object comprises a product (e.g. a cd/compact disk, stent, pill bottle).

A13. An object as set forth in Claim A1, wherein said object comprises a receptacle (e.g. a tray for holding meat), said receptacle being operable to receive and hold a product (e.g. a steak, a stent), said product having an RFID tag attached thereto and



being operable for communicating said wireless radio signals between said product and said integrated antenna in said receptacle.

A14. An object as set forth in Claim A4, said wireless RF signals having a frequency not exceeding 1 MHZ.

A15. An object as set forth in Claim A1, said integrated antenna comprising a loop integrated into said object in each of two substantially orthogonal dimensions thereof.

R1. A receptacle comprising:  
a body portion operable to hold a product,  
an RFID tag attached to said body portion, said RFID tag comprising a receiver, a transmitter, and an antenna, said antenna being integrated into a unitary relationship with said body portion.

R2. A receptacle as set forth in Claim R1, said RFID tag being operable to receive and transmit wirelessly at a frequency not exceeding 1 megahertz.

R3. A receptacle as set forth in Claim R2, said frequency not exceeding 300 kilohertz.

R4. A receptacle as set forth in Claim R3, said antenna being a loop antenna designed for superior strength of signal reception by having dimensions thereof scaled to dimensions of said body portion.

R5. A receptacle as set forth in Claim R4, said loop antenna having a dimension thereof that is substantially as large as to a maximum dimension of said receptacle.

R6.. A receptacle as set forth in Claim R5, said loop antenna comprising a loop integrated into said receptacle in each of two substantially orthogonal dimensions thereof.

R7. A receptacle as set forth in Claim 3, said receptacle comprising a container operable to enclose said product, said container further comprising a sensor disposed on a surface of said container and operable to generate a sealing signal indicating sealing of said container upon shrink-wrapping thereof.

R8. A receptacle as set forth in Claim R3, said receptacle comprising a container operable to enclose said product, said RFID tag further comprising a sensor disposed within said container and operable to generate a signal characteristic of a condition experienced by said product.

R9. A receptacle as set forth in Claim R5, said environmental condition being selected from temperature, light exposure, weight, humidity, and shock impulse (jog).

R10. A receptacle as set forth in Claim R5, said RFID tag further comprising an indicator element for indicating impending expiry of viability of said product.

R11. A receptacle as set forth in Claim R10, said indicator element being operable to provide a signal selected from visible light and audible sound.

R12. A receptacle as set forth in Claim R11, said indicator element being an LCD display.

R13. A receptacle as set forth in Claim R11, said indicator element being a blinking lamp.

R14. A receptacle as set forth in Claim R3, said RFID tag further comprising an indicator element for indicating impending expiry of viability of said product.

R15. A receptacle as set forth in Claim R3, said receptacle further comprising an indicator element operable for indicating a condition selected from a) impending expiry of viability of said product and b) sealing of said receptacle.

R16. a receptacle as set forth in Claim R15, said receptacle comprising a sensor disposed on a surface of said receptacle and operable to generate a sealing signal indicating sealing of said receptacle upon shrink-wrapping thereof.

R17. A receptacle as set forth in Claim R7, said receptacle comprising a stackable container which is adapted for stacking upon other stackable containers to expose a surface of said stackable container for visual inspection, said stackable container further comprising an indicator element disposed on said surface and operable for indicating a condition selected from a) temperature of said product, b) sealing of said receptacle, c) light exposure within said stackable container, d) weight of said product, e) humidity within said stackable container, f) jog/shock imposed on said container, and g) impending expiry of viability of said product.

R18. A receptacle as set forth in Claim R17, said indicator element being operable to provide a signal selected from visible light and audible sound.

R19. A receptacle as set forth in Claim R18, said indicator element being an LCD display.

R20. A receptacle as set forth in Claim R18, said indicator element being a blinking lamp.

R21. A receptacle as set forth in Claim R4, said receptacle comprising a pallet operable to hold a plurality of containers as set forth in Claim R8, R10, or R14, said antenna having a dimension thereof that is substantially as large as a maximum dimension of said pallet.

M1. A method of tracking the conditions of products, each said condition being selected from temperature, product enclosure (shrink-wrapping), light level, product weight, humidity, jog, product age/expiry, and product location (GPS coordinates), said method comprising the steps of :

- a) placing each product onto a first receptacle, said first receptacle being provided with a sensor for a said condition and a passive RFID tag operable to emit first wireless signals that indicate a said condition of said product,
- b) placing said first receptacle into a second receptacle, said second receptacle being provided with a sensor for a said condition and an active RFID tag operable to receive said first signals and to emit second signals, at a wireless frequency not exceeding 15 megahertz, that indicate a said condition of a first or second receptacle,
- c) detecting signals selected from said first signals and said second signals.

M2. A method as set forth in Claim M1, and further comprising the step of :  
e) providing a visual or audible indication of a said condition.

M3. A method as set forth in Claim M1, said first receptacle comprising a first antenna integrated therewith.

M4. A method as set forth in Claim M3, said second receptacle comprising a second antenna integrated therewith.

M5. A method of tracking the conditions of products, each said condition being selected from temperature, product enclosure (shrink-wrapping), light level, product weight, humidity, jog, product age/expiry, and product location (GPS coordinates), said method comprising the steps of :

- a) integrating a passive RFID tag with a product, said passive RFID tag comprising a product antenna integrated into said product, said RFID tag being operable to emit wireless RF identification (ID) signals operable to identify said product in response to a wireless RF interrogation signal;
- b) placing said product onto a first receptacle, said first receptacle being provided with a sensor for a said condition and an active RFID tag operable to emit said RF interrogation signal, to receive said ID signals, and to emit first RF signals operable to identify said product and to indicate a said condition at said first receptacle,

- c) placing said first receptacle into a second receptacle, said second receptacle being provided with a sensor for a said condition and an active RFID tag operable to receive said first signals and to emit second RF signals that indicate a said condition at one of said first and second receptacles,
- d) detecting audible signals selected from said first RF signals and said second RF signals
- e) transmitting audible signals (e.g. by cable or by high frequency RF) detected at step (d) to a central station for audible recording thereat (e.g. on a write-once-only CD ).

M6. A method as set forth in Claim M5, and further comprising the step of :

- e) providing a visual (e.g. on an LCD display) or audible (e.g. an alarm bell) indication of a said condition.

M7. A method as set forth in Claim M5, said first receptacle comprising a first antenna integrated therewith.

M8. A method as set forth in Claim M7, said second receptacle comprising a second antenna integrated therewith.

M9. A method as set forth in Claim M1 or Claim M5, said RF signals having a frequency not exceeding 1 megahertz.

S1. A system of tracking the conditions of products, each said condition being selected from temperature, product enclosure (shrink-wrapping), light level, product weight, humidity, jog, product age/expiry, and product location (GPS coordinates), said system comprising:

- a) a passive RFID tag integrated with a said product, said passive RFID tag comprising a product antenna integrated into said product, said RFID tag being operable to emit wireless RF identification (ID) signals operable to identify said product in response to a wireless RF interrogation signal;

- b) a first receptacle operable to hold said product, said first receptacle being provided with a sensor for a said condition and an active RFID tag operable to emit said RF interrogation signal, to receive said ID signals, and to emit first RF signals operable to identify said product and to indicate a said condition at said first receptacle,
- c) a second receptacle operable to hold said first receptacle, said second receptacle being provided with a sensor for a said condition and an active RFID tag operable to receive said first signals and to emit second RF signals that indicate a said condition at one of said first and second receptacles,
- d) a field antenna operable to detect auditable signals selected from said first RF signals and said second RF signals
- e) a transmitter operable to transmit auditable signals (e.g. by cable or by high frequency RF) detected at step (d) to a central station (e.g. via a satellite) for auditable recording thereof (e.g. on a write-once-only CD ).

S2. A method as set forth in Claim S1, said system further comprising:

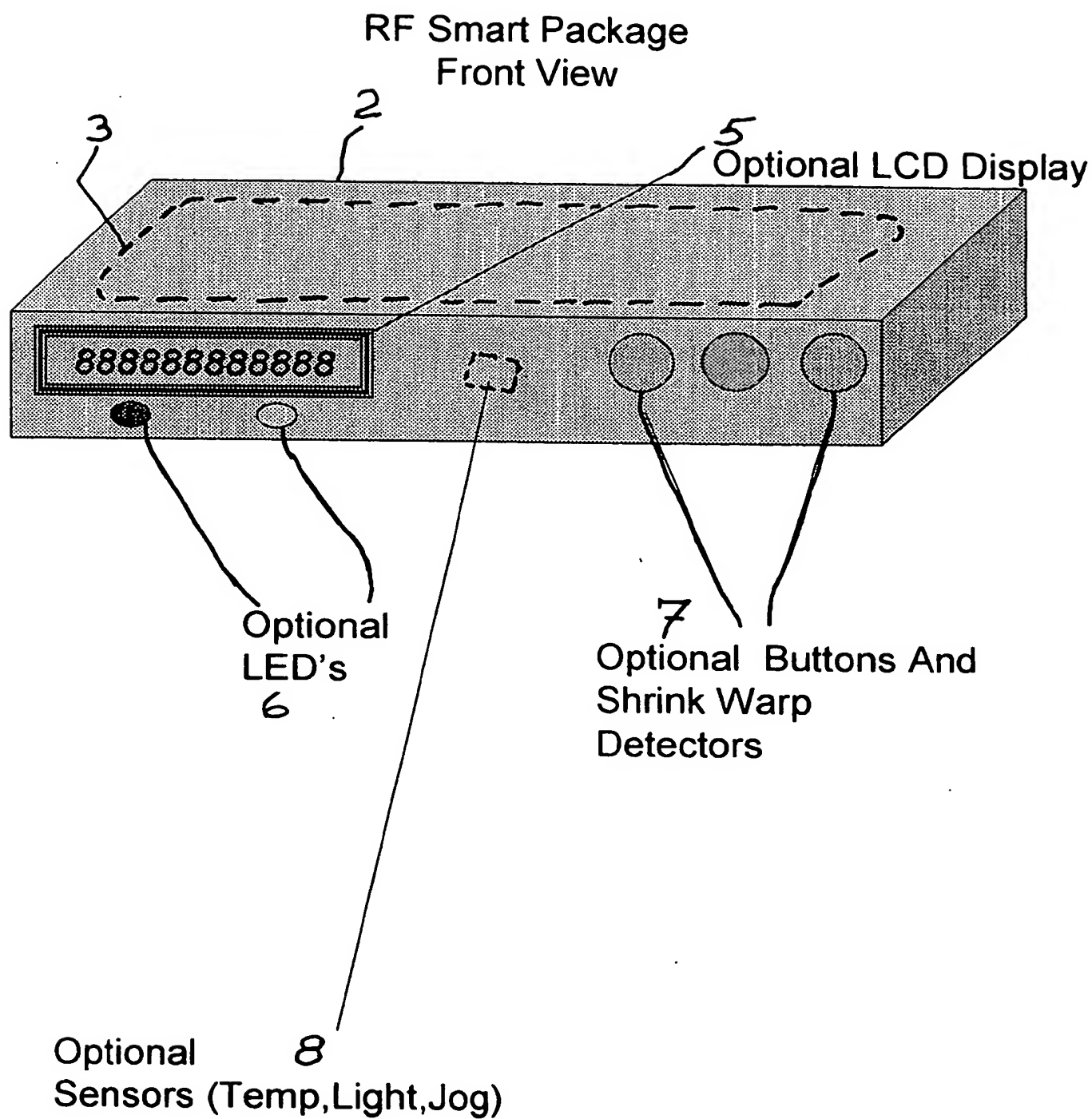
- e) an indicator operable to providing a visual (e.g. on an LCD display) or audible (e.g. an alarm bell) indication of a said condition.

S3. A method as set forth in Claim S1, said first receptacle comprising a first antenna integrated therewith.

S4. A system as set forth in Claim S3, said second receptacle comprising a second antenna integrated therewith.

S5. A system as set forth in Claim S4, said RF signals having a frequency not exceeding 15 megahertz.

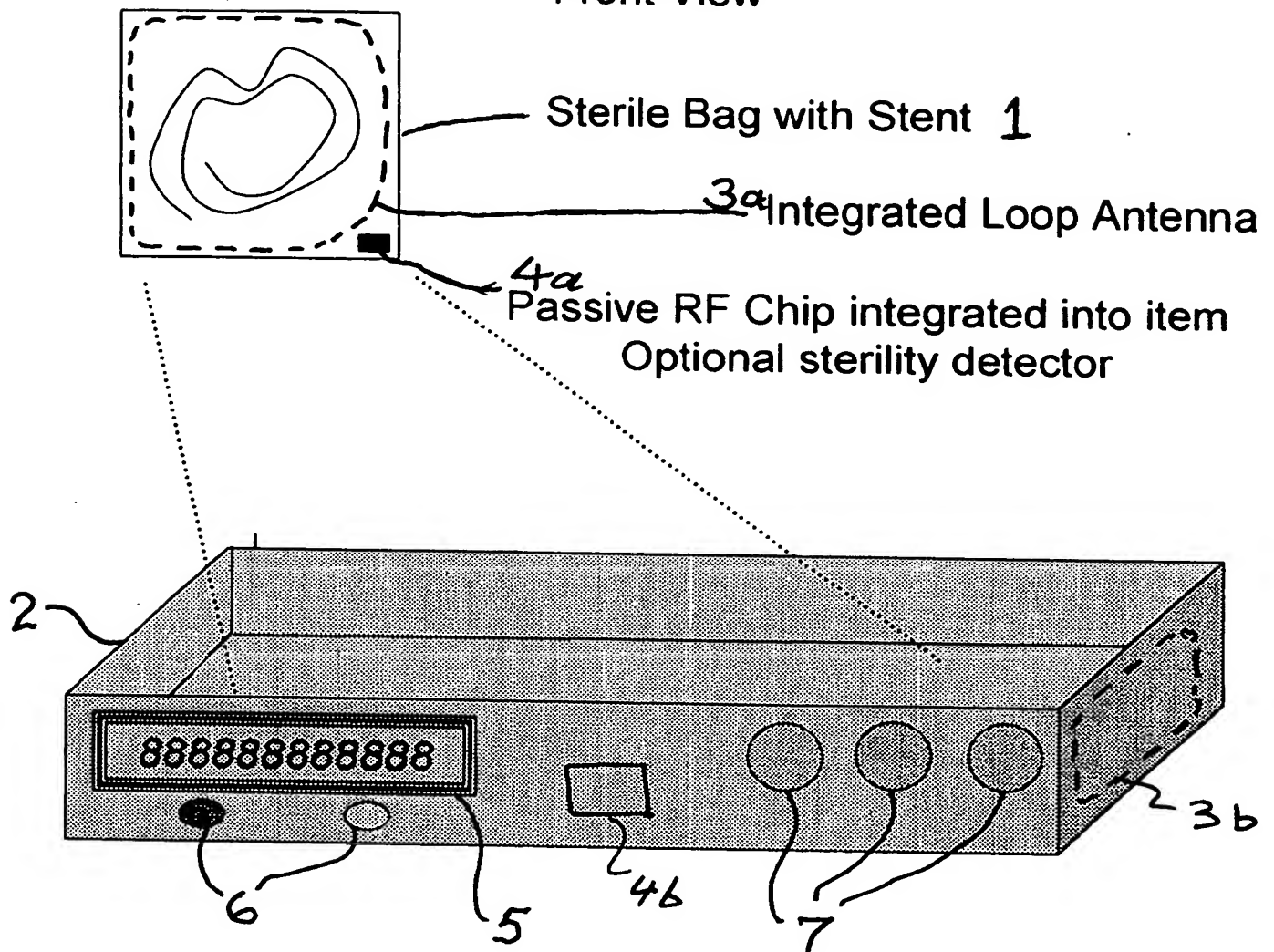
S6. A system as set forth in Claim S4, said first receptacle comprising a stackable box, said second receptacle being selected from a pallet, a ULD Unit Load Device), and a warehouse shelving unit



**Confidential**

**Figure 1**

RF Smart Tote/Package With One Item  
Front View

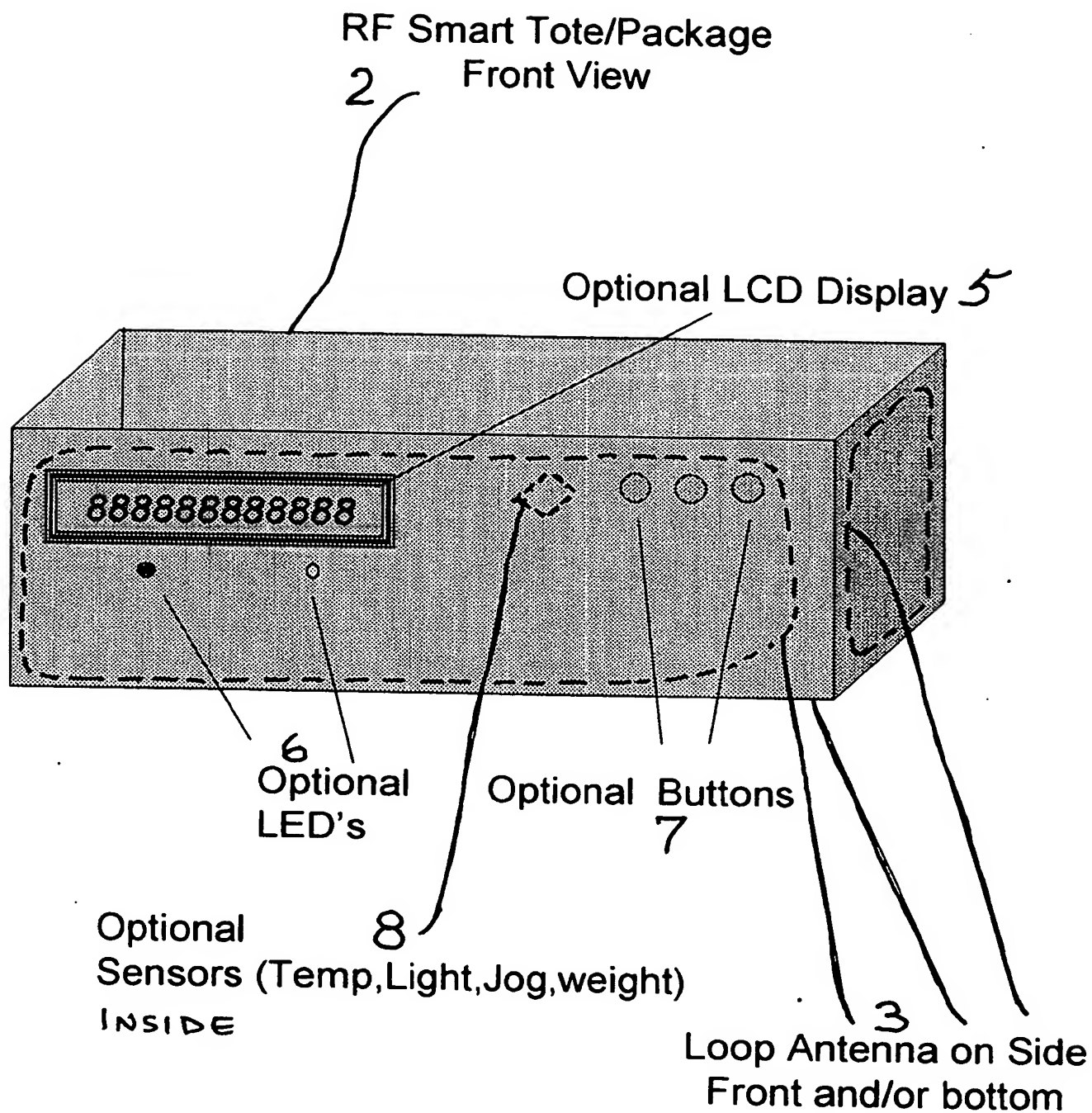


Stents or other medical devices with passive RF  
systems placed into active smart package

Confidential

Figure 2

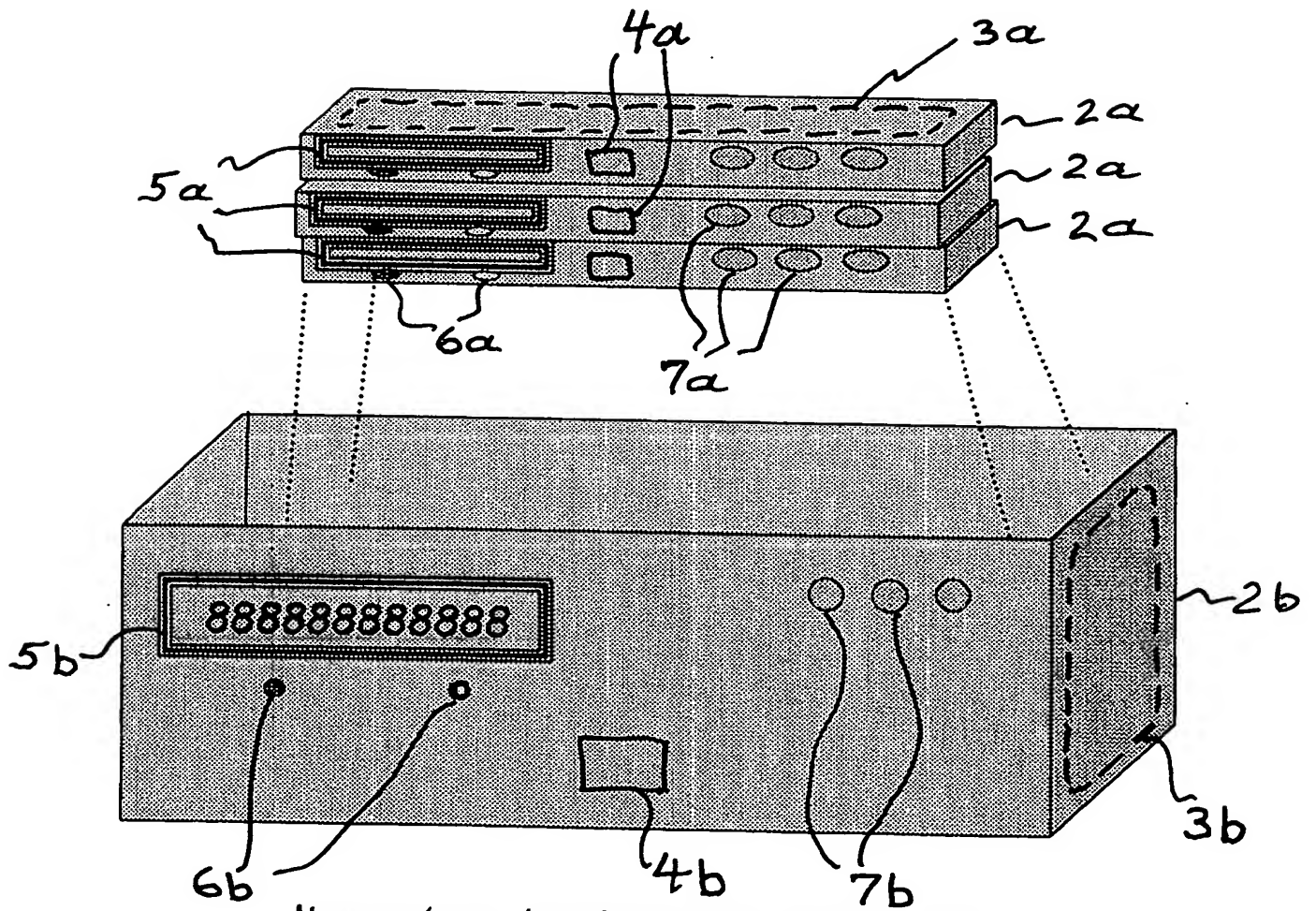




*Confidential*

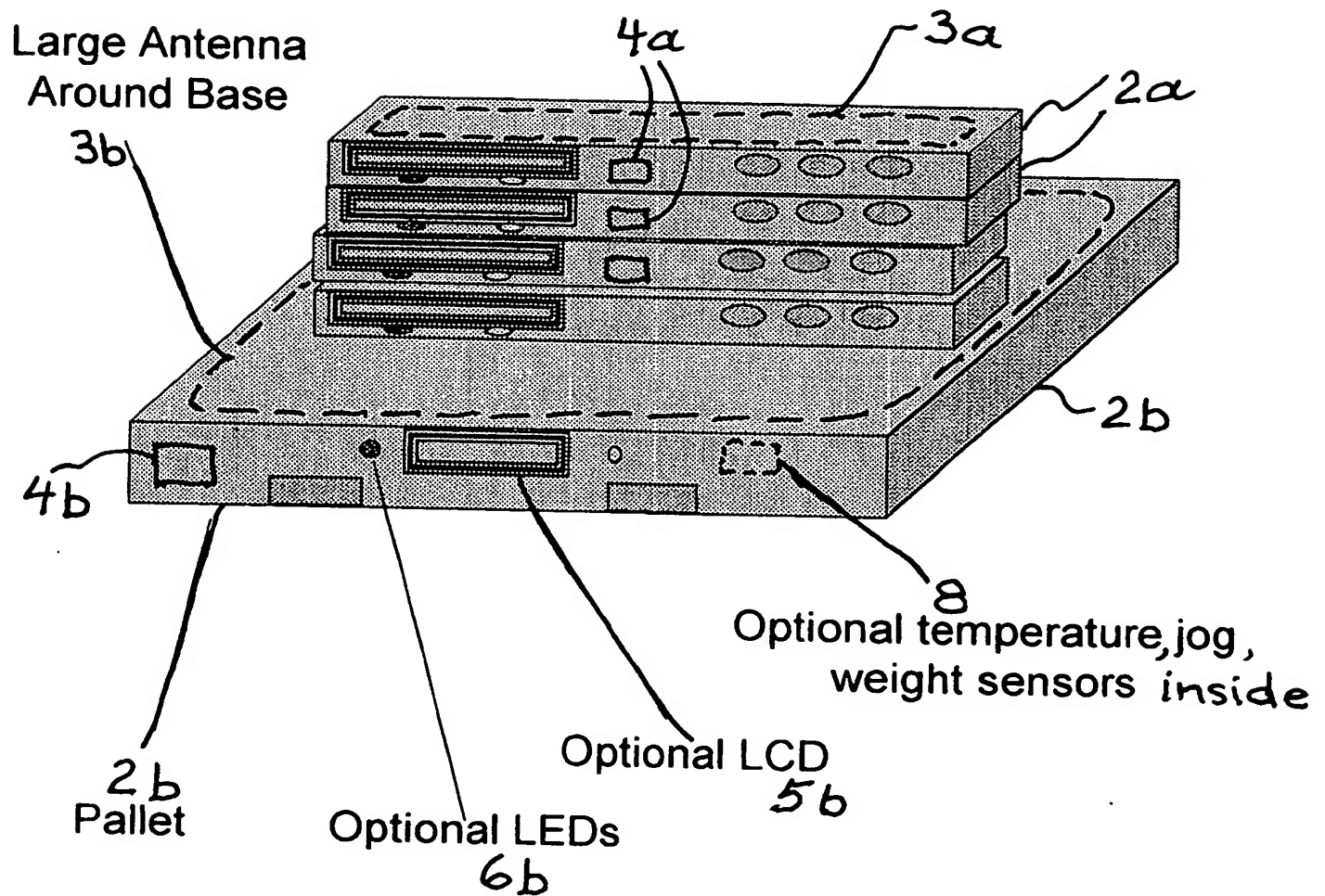
**Figure 3**

# RF Smart Tote/Package Front View



Items (e.g. bottles) with active RF  
Integrated systems placed into active smart tote  
for shipping and tracking

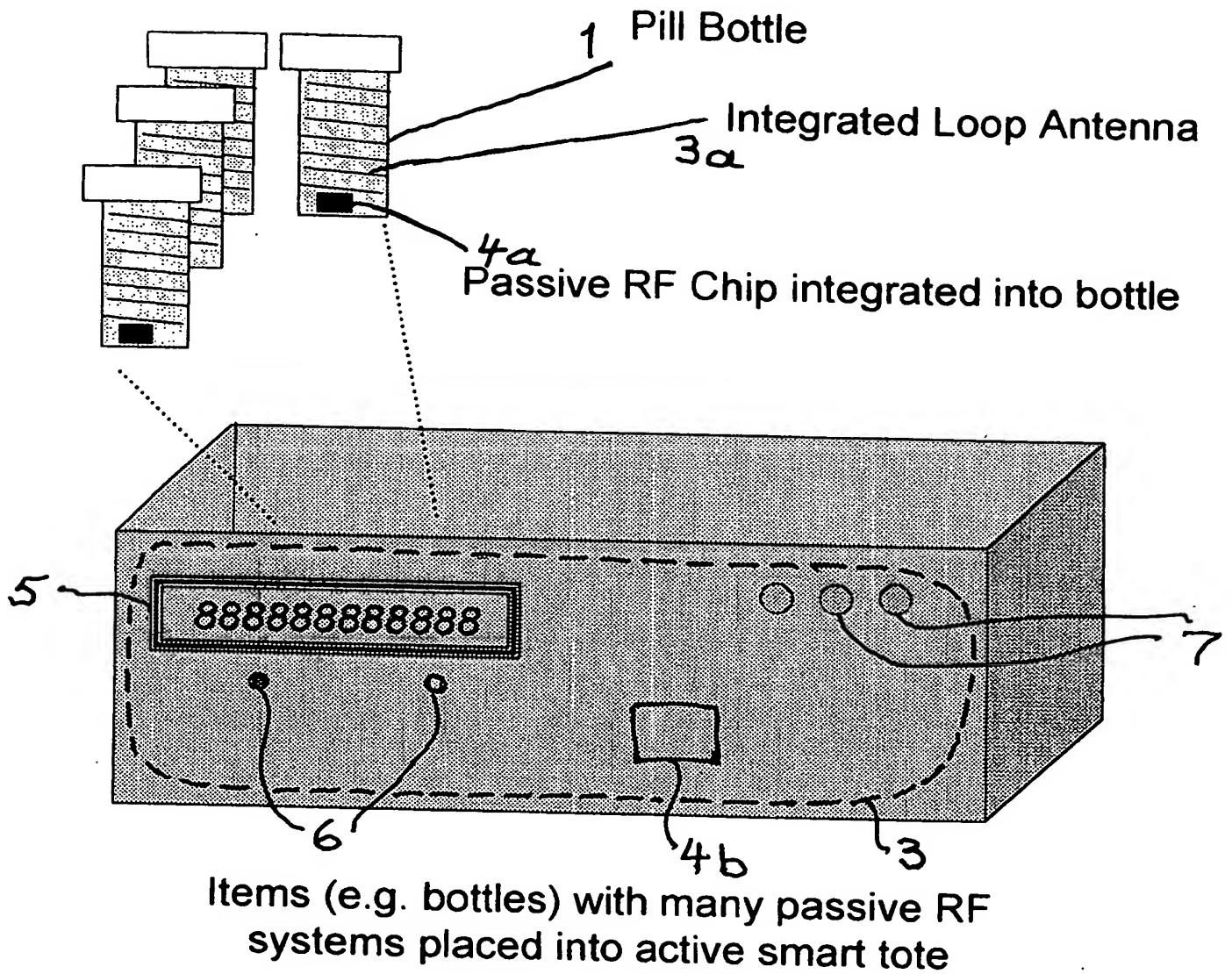
# RF Smart Pallet/Package Front View



Confidential

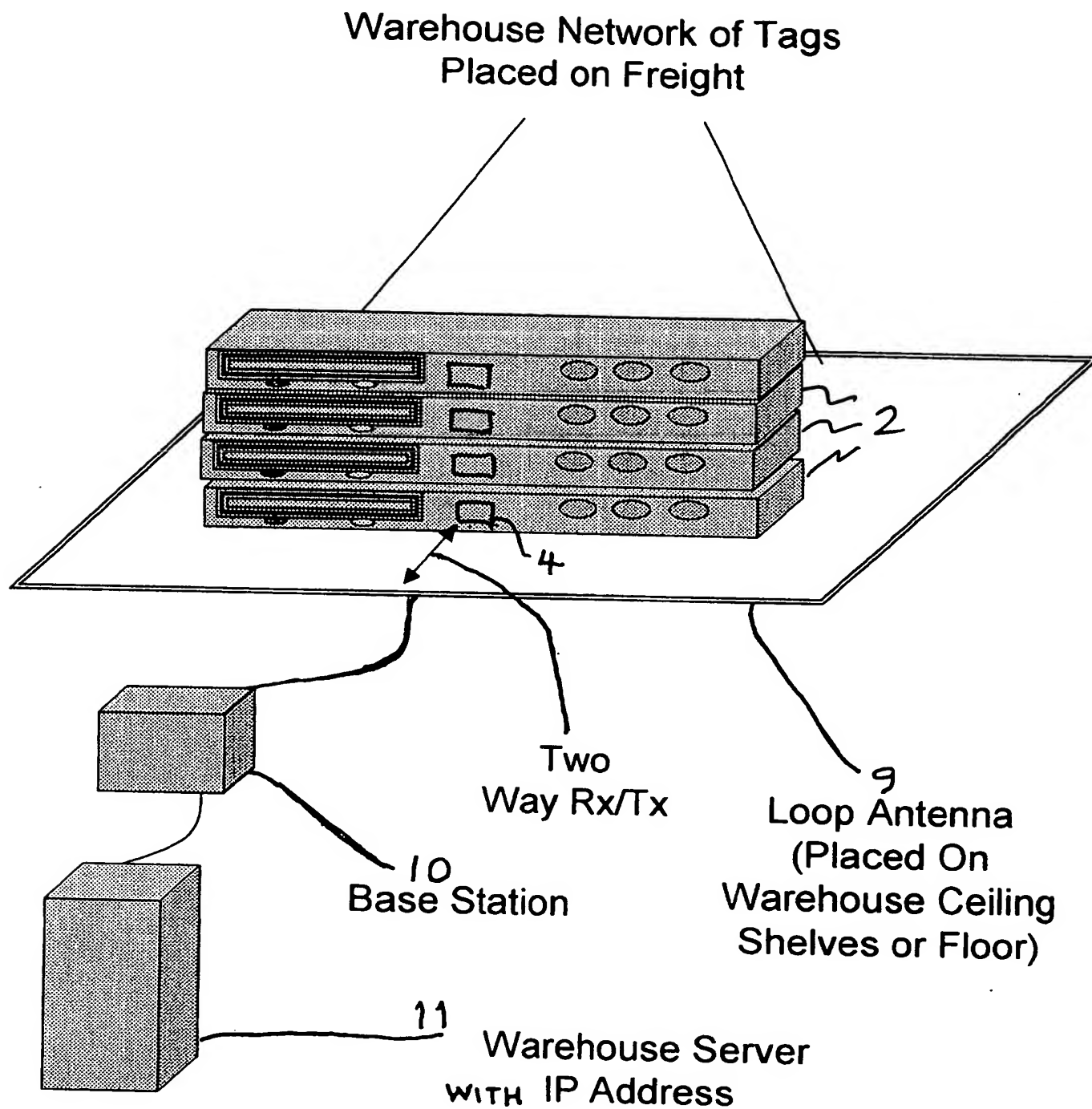
Figure 5

RF Smart Tote/Package With Many Items  
Front View



Confidential

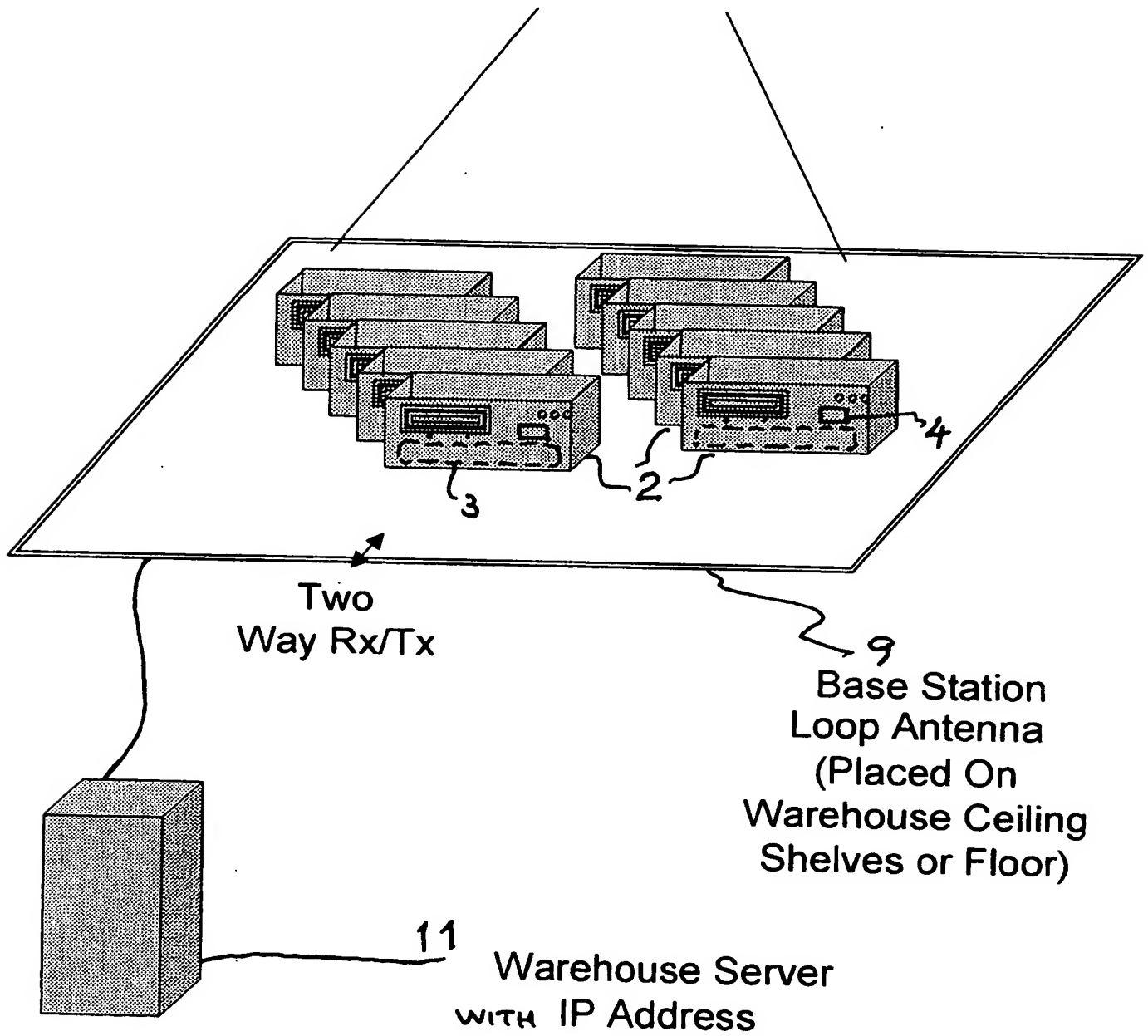
Figure 6



**Confidential**

**Figure 7**

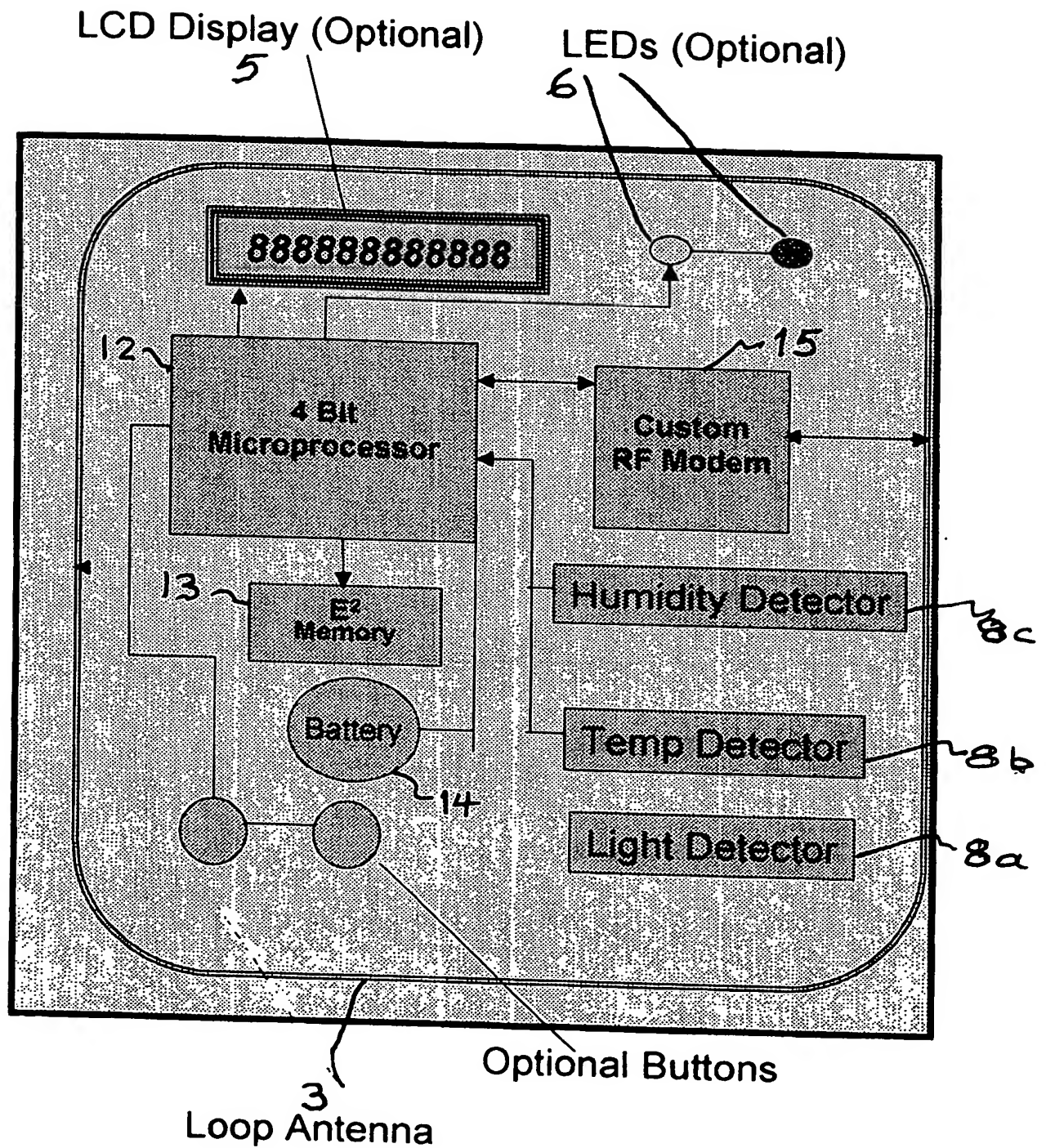
# Warehouse Network of Tags Placed on Freight



Confidential

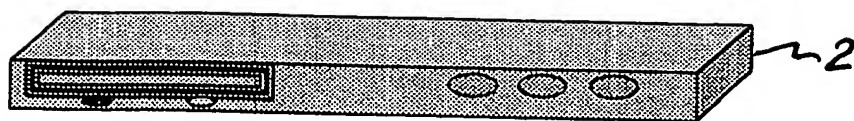
Figure 8

# Smart Package Block Diagram



Confidential

Figure 9



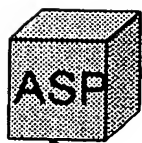
### Data Log in Pack Memory

Date, Time Temp. Light  
Date, Time Temp. Light  
Date, Time Temp. Light

.

.

.



16



17

### Data Log in Remote ASP Memory

GPS Location, Date, Time Temp.  
GPS Location, Date, Time Temp.  
GPS Location, Date, Time Temp.  
GPS Location, Date, Time Temp.  
GPS Location, Date, Time Temp.

.

.

.

Confidential

Figure 10



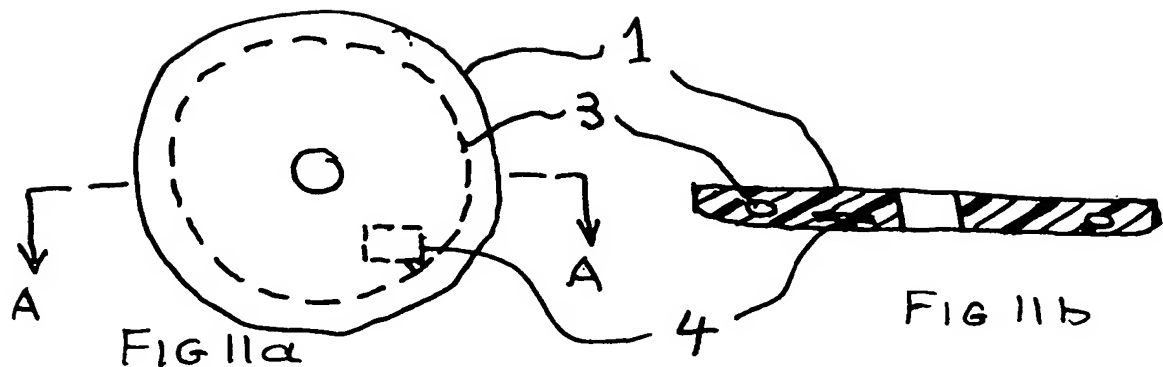


FIG 11

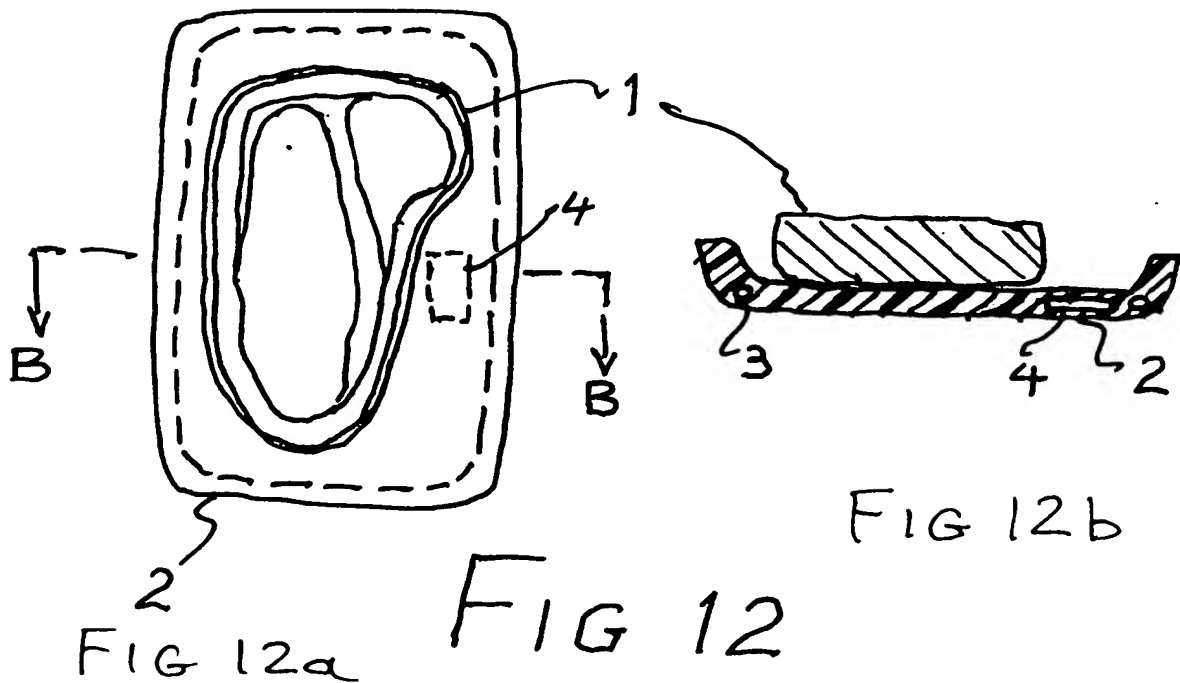
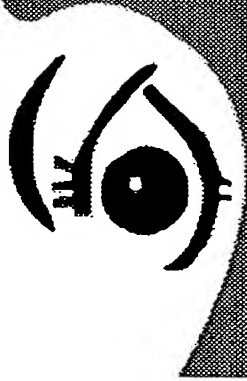


FIG 12



**Visible Assets Inc.**  
Real Time Asset Intelligence

## *Pre - July 21/04 Briefing*

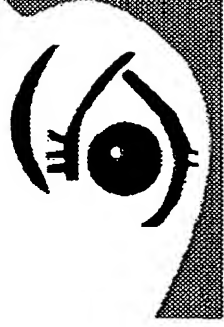
Confidential – All information contained is property of Visible Assets Inc., and is not for duplication or distribution

# **Current Issues Facing Medical Device Distributors**

- FDA 21CFR Part 11, 820.150 160, 181, 184 and 821.20 regulations on product tracking and records audits are increasingly difficult to comply with in a systematic, cost efficient manner.
- Product pedigree data difficult to accurately maintain, to access and to take action on.
- Three month shelf life leads to high past code-date product levels and waste.
- Manual maintenance of hospital inventory levels are costly and make poor use of sales staff time.
- Consignment selling leads to high inventory investment in hospitals.

# Current Solutions and Challenges

Issues	Current Solutions	Challenges
FDA 21CFR Part 11, 820.150, 181,184, 160 and 821.20 regulations on product tracking and records audits are increasingly difficult to comply with in a systematic, cost efficient manner.	Manual processes mixed with RFID technology and data loggers.	Most RFID tech not usable in warehouses or manufacturing environments, leading to costly semi automated IT solutions. Data loggers are expensive and require implementation of awkward, complex process in order to comply with FDA.
Product pedigree data are difficult to accurately maintain, to access and to take action on.	EPC tags and readers.	EPC pedigree tags expensive and unreliable. Very limited use in production settings to date.
Three month shelf life leads to high past code-date product levels and waste	EPC tags and readers	As above
Manual maintenance of hospital inventory levels costly and poor use of sales staff time	Mobile Aspects or Pyxis style systems	Only tracks inventory levels in the hospital, not across supply chain. Hospital face both hi capital costs and hi proprietary software costs.
Consignment selling leads to high inventory investment in hospitals	As above	As above



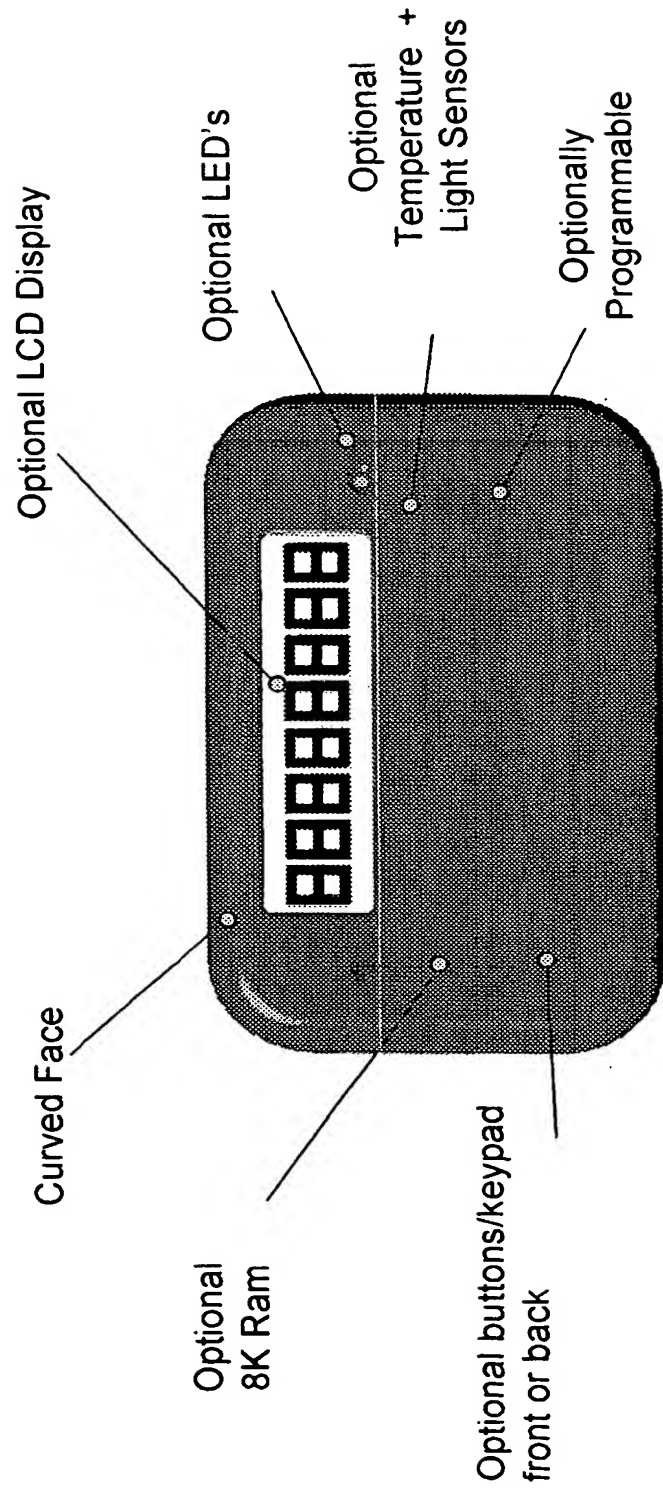
**Visible Assets Inc.**  
Real Time Asset Intelligence

## **Solutions**

- **Integrated, Online Asset Visibility and Pedigree**
- **21CFR Part11 electronic audits for 820 and 821**
- **Asset Status, Change of Possession, Proof Of Delivery, Product Pedigree**
- **Event Verification and Settlement**

# The Technology

## t-Tags™ for Product Tracking

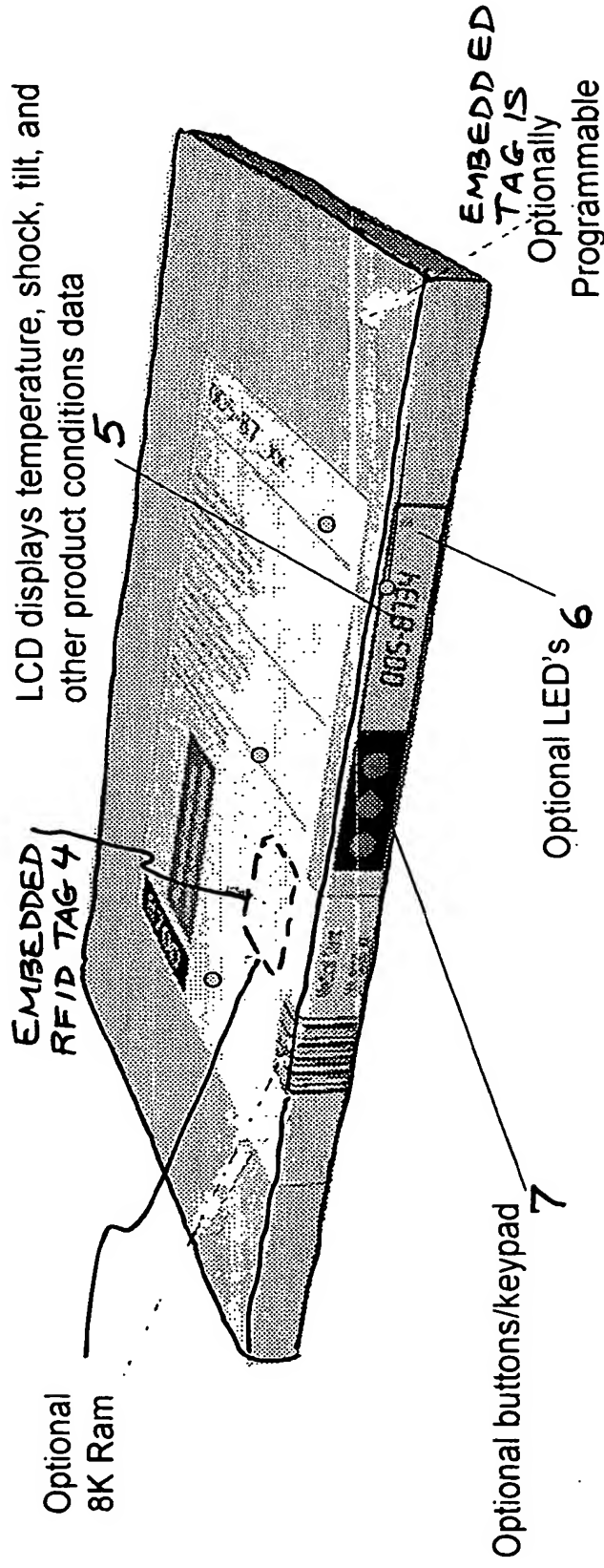


(Credit card size and 0.2 inch thick)

Each t-Tag is actually a low cost credit-card size low cost, stand alone wireless, four bit, networked programmable, “asset computer” that can fit easily and be applied to product during or post manufacturing with a full RF network capability and 10 year proven battery life

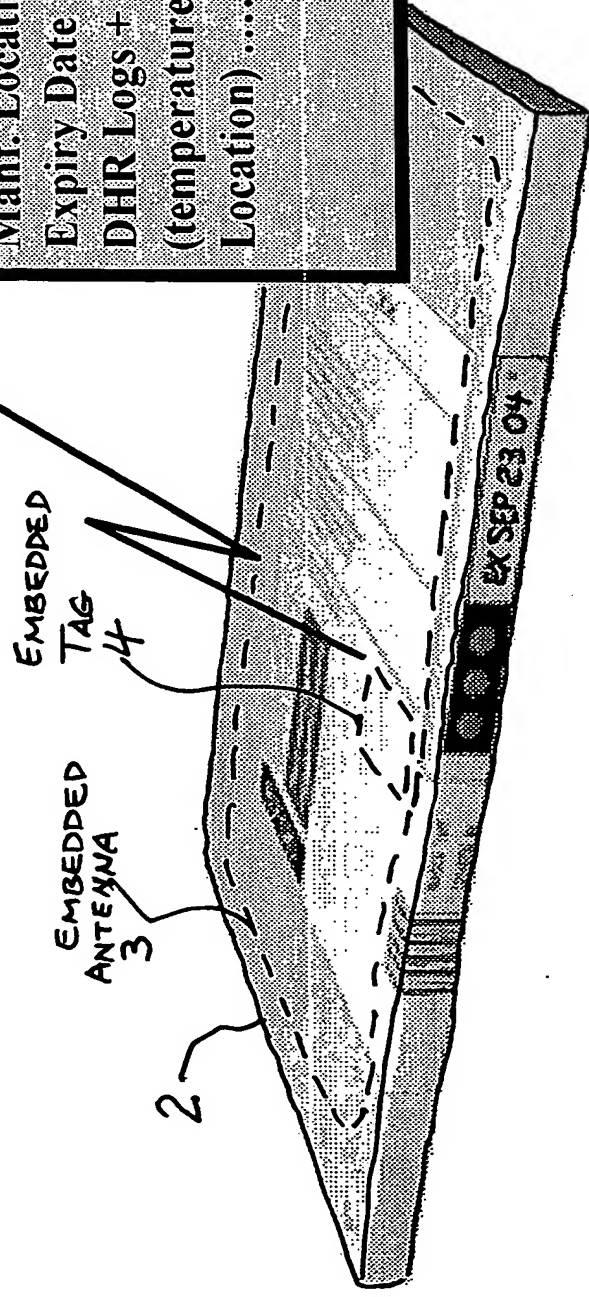
# The Technology

## t-Pak™ for Stents and other High Value Medical Devices



Each t-Pak is actually a t-Tag integrated into a re-usable package. A low cost, stand alone RF networked, programmable, “smart box” with same features as t-Tags. Tracks temperature, opened/closed box’s, location of box and reports back in real time to on-line systems. The t-Pak can be remotely programmed to say or do anything over the web.

**t-Pak - A low cost “smart” package. Has 4 bit processor, 8K Ram and RF network links. data sensors + data loggers.**



## ***The Product Pedigree***

**21CFR Part11 “OK”**

**Stored in t-Pak memory**

**Model Number**

**Serial Number**

**Lot Number      Lot Specs**

**No. Units in Lot**

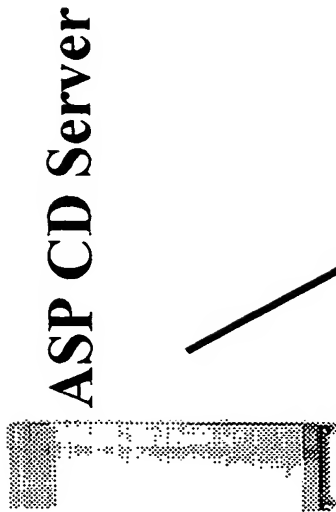
**Manf. Date**

**Manf. Location**

**Expiry Date**

**DHR Logs + Data Logs.....  
(temperature, closed/opened,  
Location) .....**

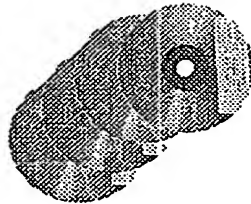




ASP CD Server

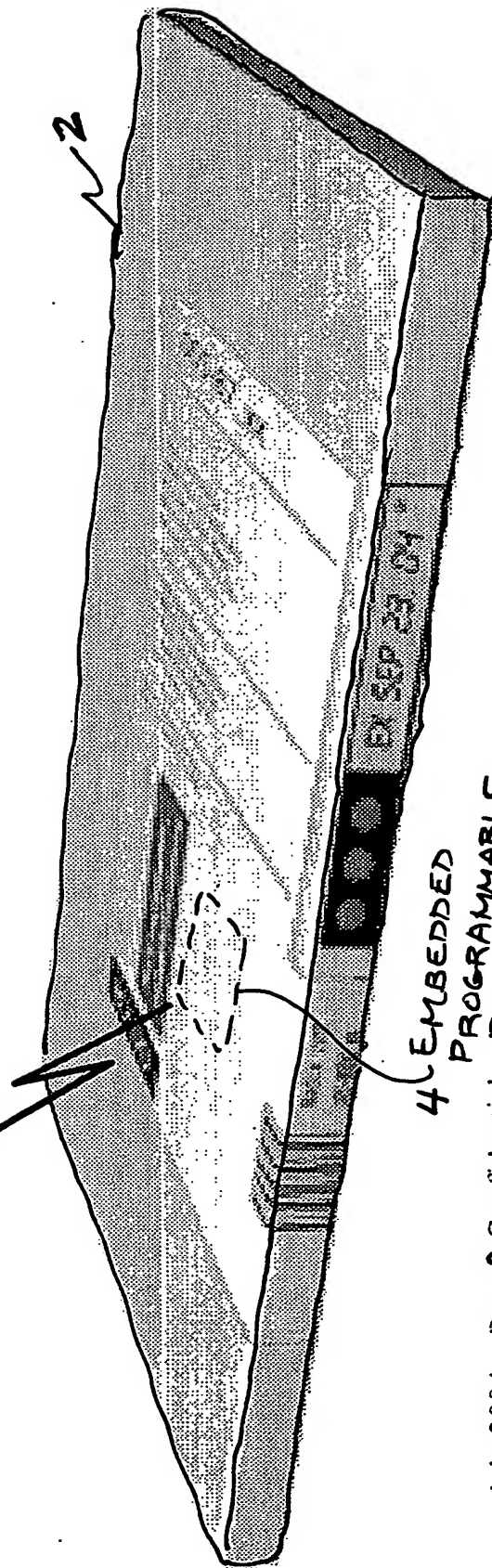


Phone/Cell/Satellite



To RO-CD many times/day  
+ NIST Time Date Stamp

VAI "Touchless" Reader



4 EMBEDDED  
PROGRAMMABLE  
RFID TAG

### a. Web Enabled Online Status Reports

## c. 21CFR Part11 Compliant Audit Trial

July 2004 Page 9 Confidential

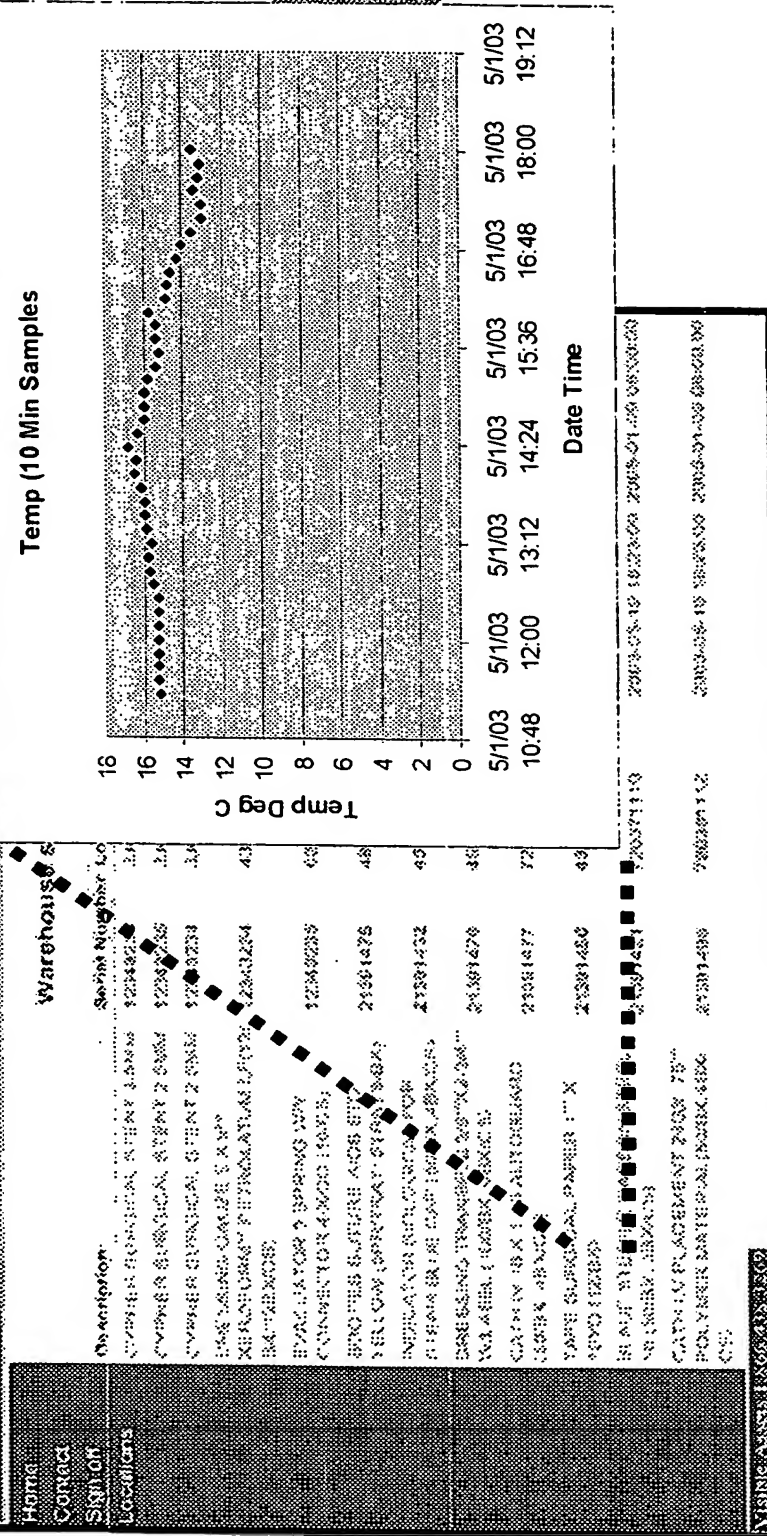
# “Air Traffic Control For DES Stents”

a. Web Enabled Online Status Reports

b. Exportable Events

c. 21CFR Part11 Compliant Audit Trial

## Visible Assets Real Time Asset Tracking





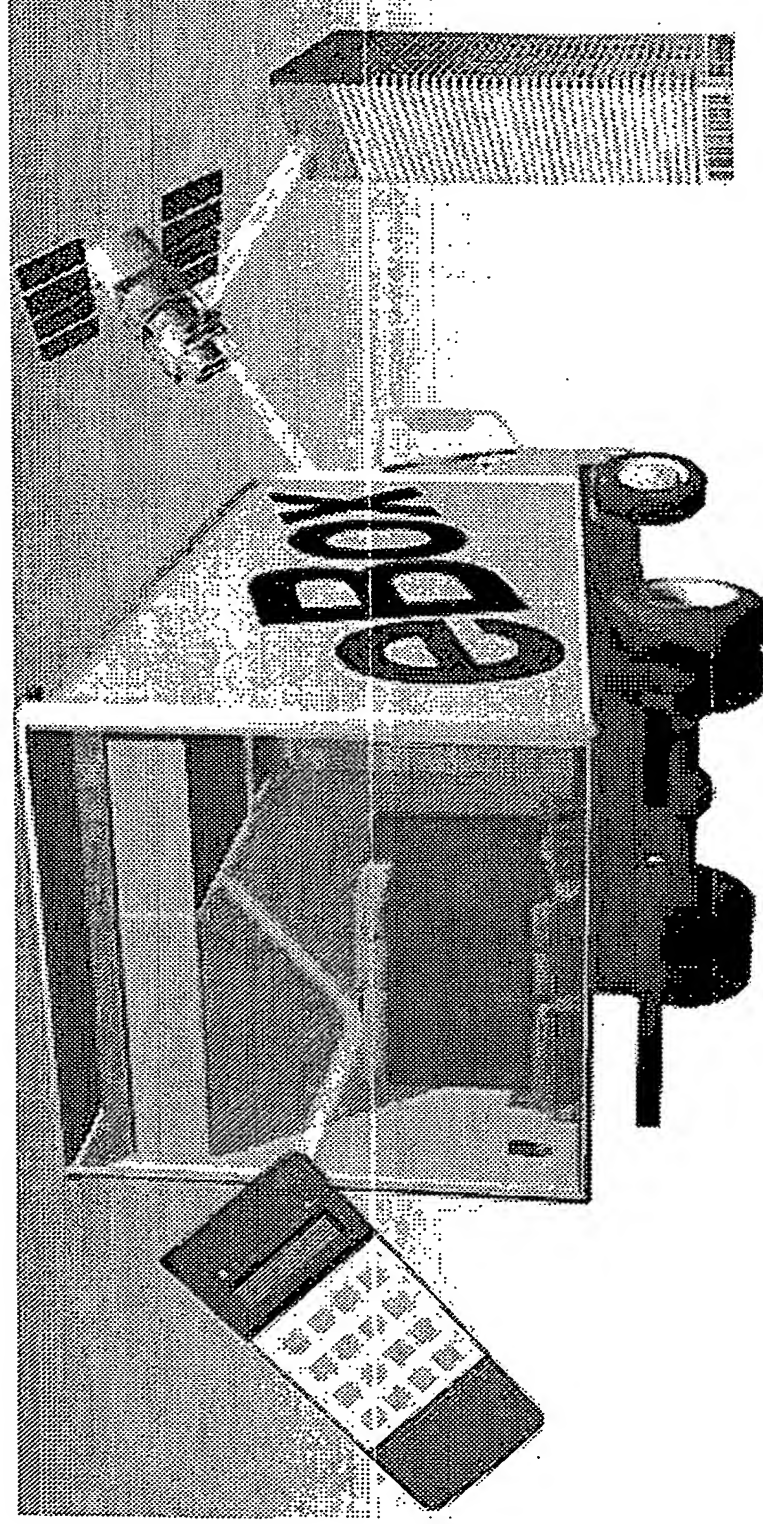
**Visible Assets Inc.**  
Real Time Asset Intelligence

## **The Systems**

- **Line Haul**
- **Distribution Center**
- **Regional Delivery**
- **Hospital Dispensary**

# The Systems

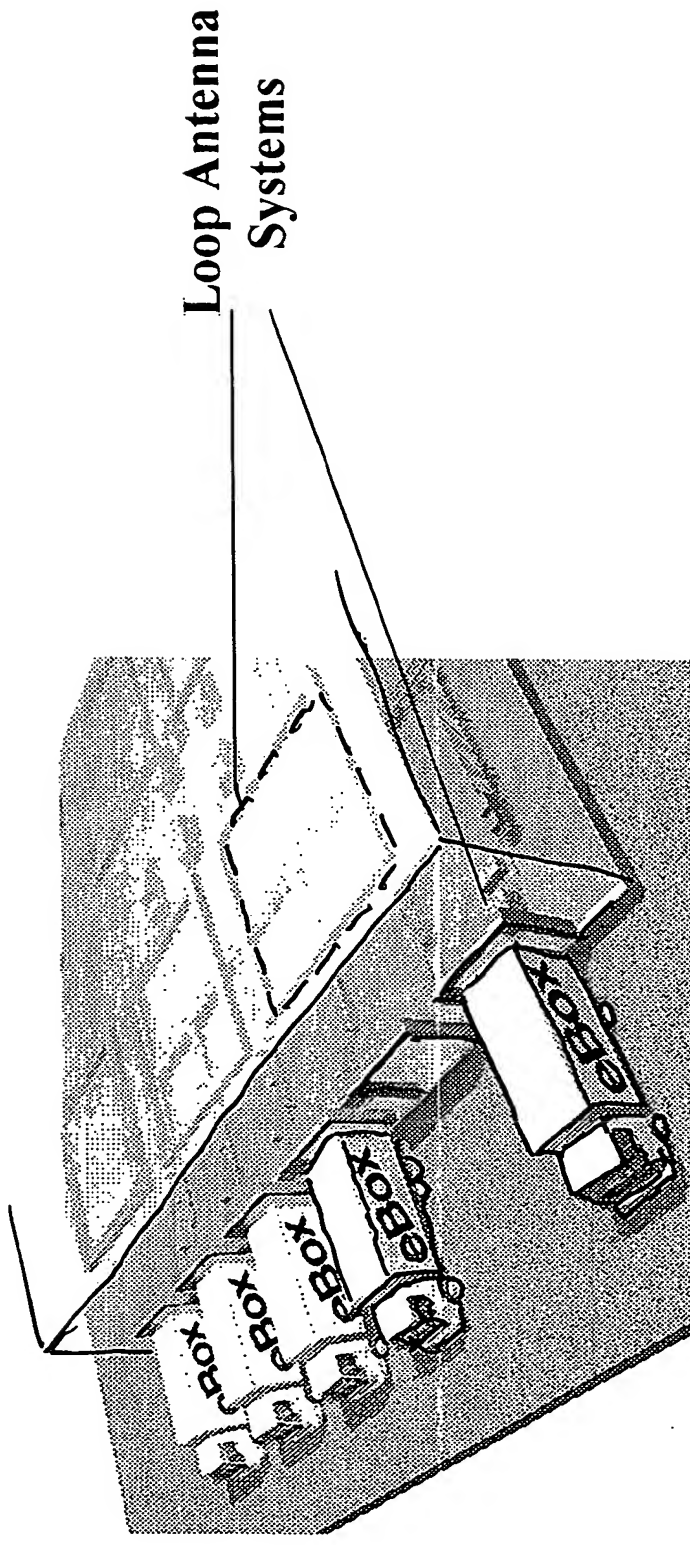
## Tamper proof FDA Compliance During Line Haul



VAI provides low cost readers in vehicles that make tamper proof, real time temperature and status tracking for Medical assets exceed 21CFR Part 11 audit standards.

# The Systems

Simple low cost Readers in Distribution Centers

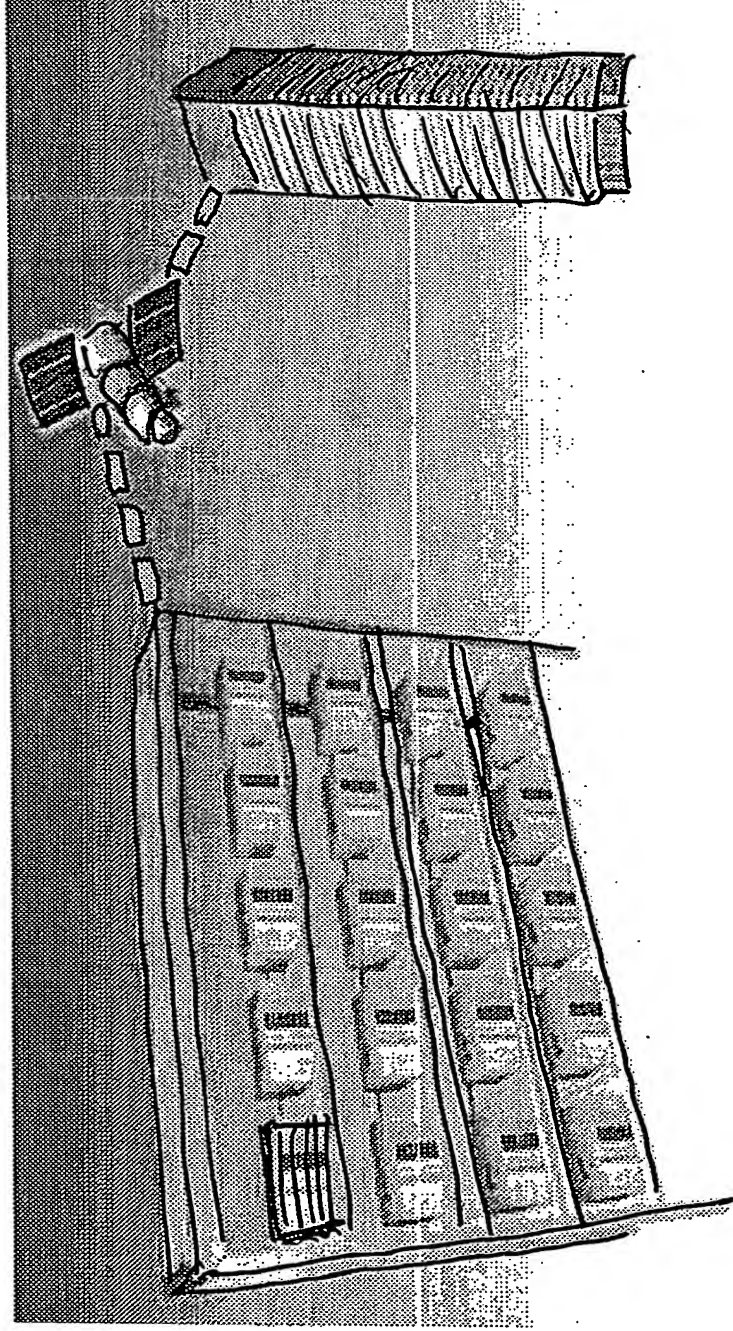


Unique loop antenna system provide range, reproducibility, reliability in harsh environments. Our engineers have installed systems with over 10,000 working tags in 80,000 sq foot facilities.



# The Systems

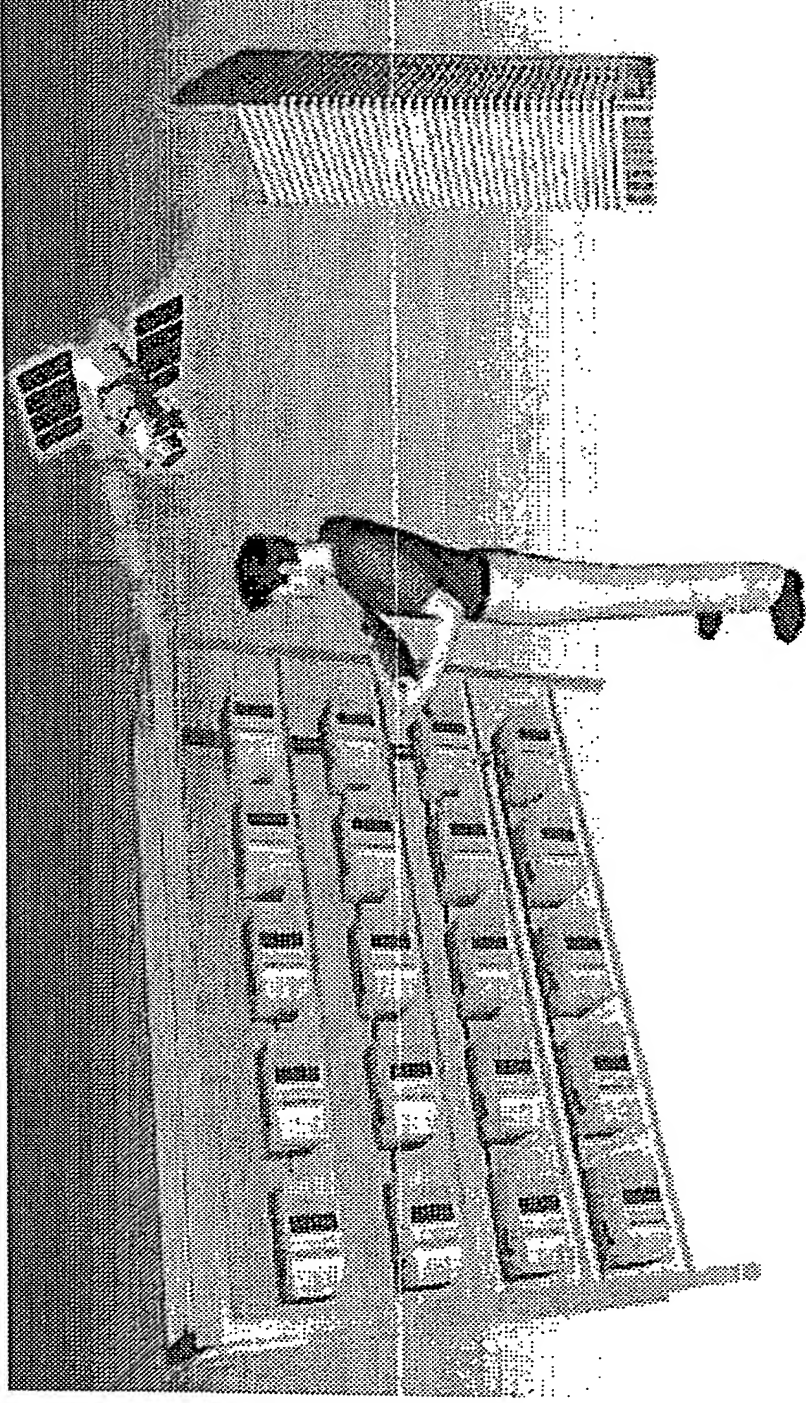
## Simple Low Cost Readers in Distribution Center and/or Hospital



VAI have unique readers that work reads and writes to t-Paks on shelf in real time using special loop antennas

# The Systems

## Simple Low Cost Readers in Distribution Center and/or Hospital

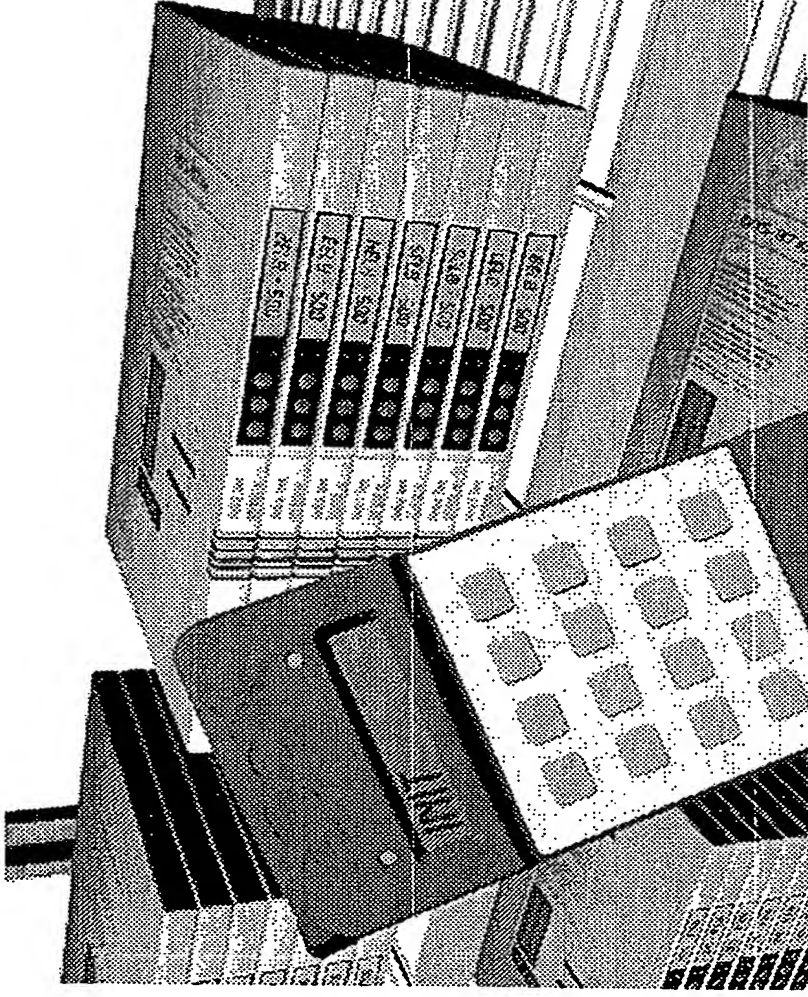


Shelf based readers may be controlled locally or remotely – each has in IP address and is a client within a large network.



# The Systems

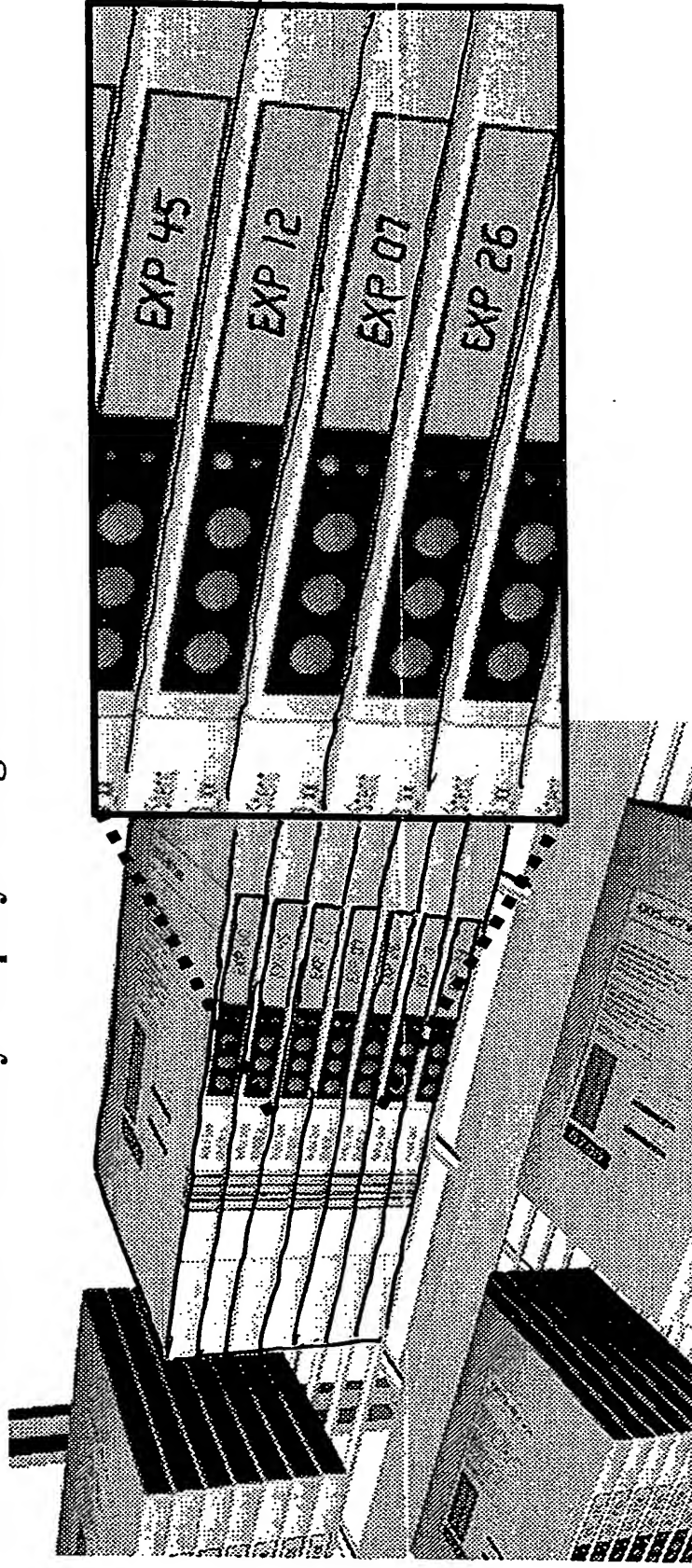
## t-Paks™ Actively Display Pedigree and other Information



Hand held may be used to read or control what is displayed on t-Pak

# The Systems

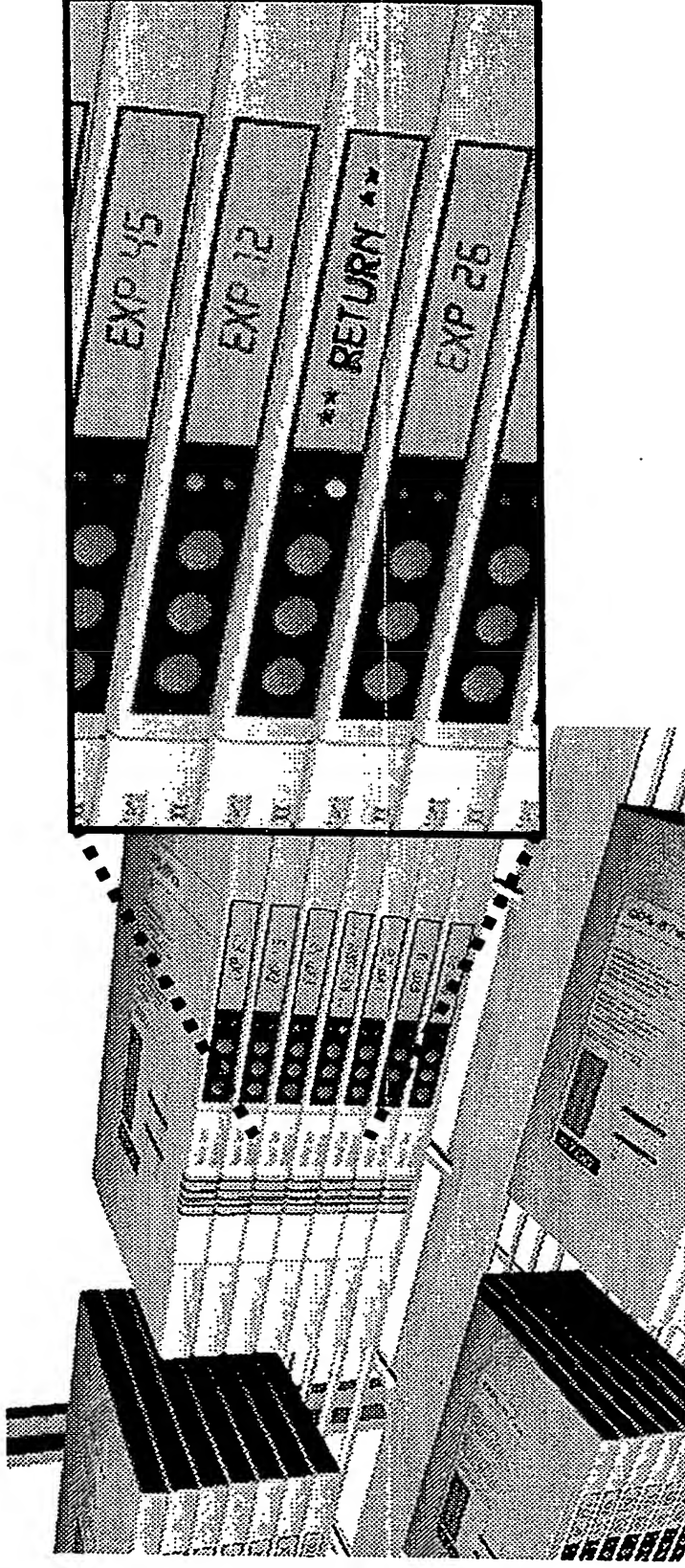
t-Paks™ Actively Display Pedigree and other Information



T-Paks may be set to display days to expire and LED's can be flashed if under threshold. This may be done remotely or locally.

# The Systems

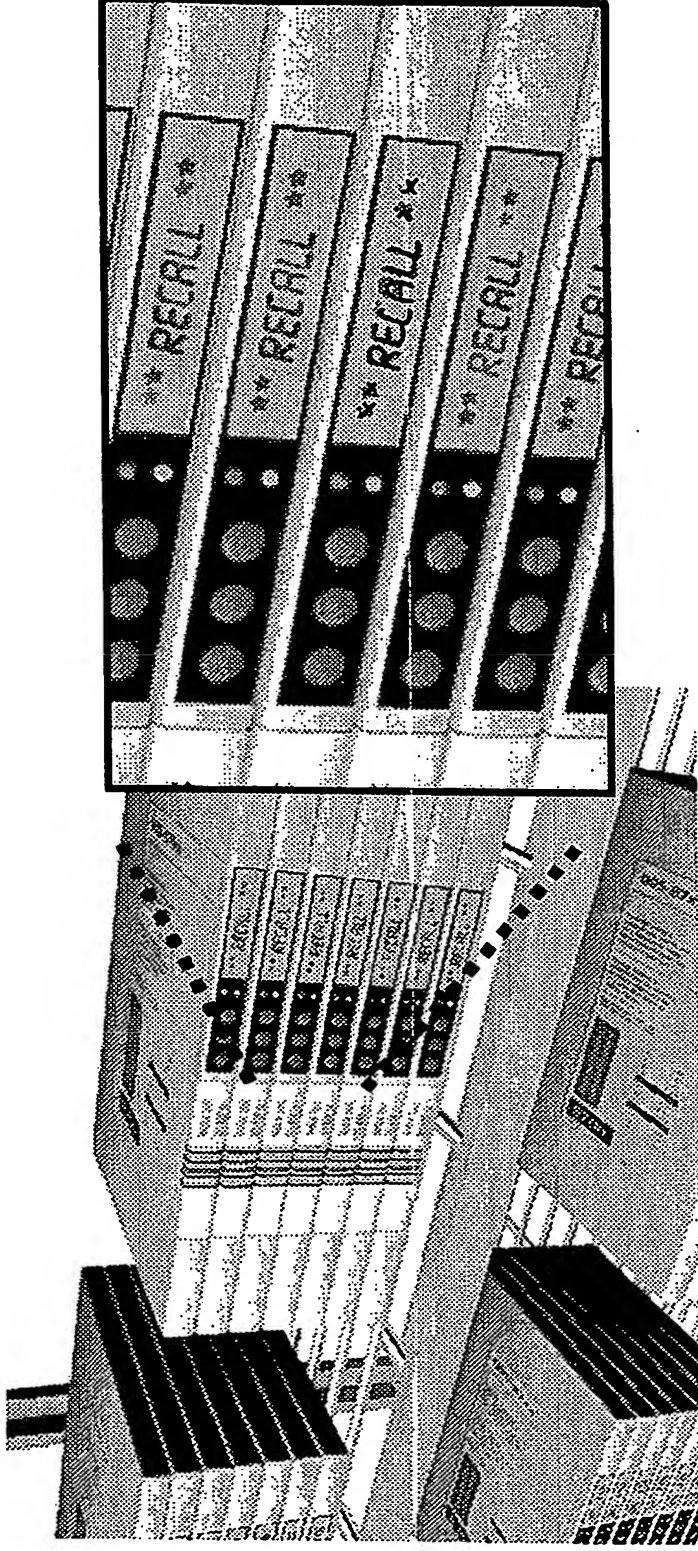
t-Paks™ Actively Display Pedigree and other Information



t-Paks may be set to display “return” when close to expiry date for shipment to another site. All information required to ship, location waybill etc can be placed in tag remotely. Only local requirement is that unit be picked.

# The Systems

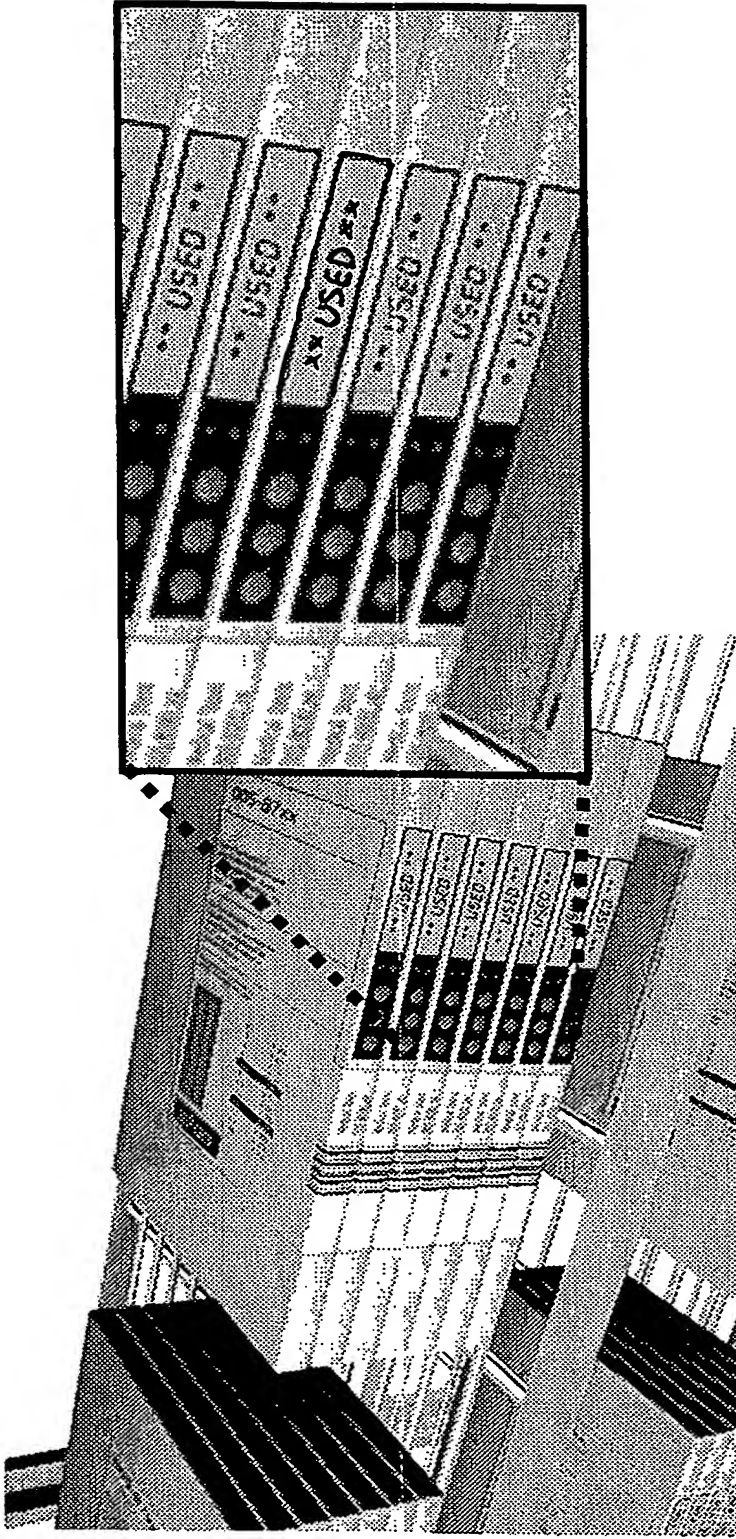
## t-Paks™ Actively Display Pedigree and other Information



If recall becomes necessary for any reason, the t-Paks may be set to display “recall” remotely with return information stored in tag. Both green and red LEDs maybe made to flash.

# The Systems

## t-Paks™ Actively Display Pedigree and other Information



After t-Paks have been used and opened they are placed back on the shelf in one section with “used” status on the LCD display. All information required for return is contained in the tag.



# Visible Assets Inc. Solutions

Issues	Visible Assets Inc. Solutions
FDA 21CFR Part 11, 820.150, 160, 181, 184 and 82.20 regulations on product tracking and records audits are increasingly difficult to comply with in a systematic, cost efficient manner.	t-Pak track pedigree, temperature and other product conditions data in real time from manufacturer to hospital. Touchless paperless, open source VAI processes make FDA compliance straightforward with almost no internal IT requirements.
Product pedigree data difficult to accurately maintain, to access and to take action on.	t-Pak' full pedigree data accessible in real time via the web or PDA. Currently in production use in critical parts and automotive sectors. t-Tags easy to apply to any product during or post manufacturing.
Three month shelf life leads to high past code-date product levels and waste	t-Pak generate alerts based on expiry date, lot, temperature and other parameters so product can be used or rotated before void.
Manual maintenance of hospital inventory levels are costly and make poor use of sales staff time	VAI solutions requires very minimal changes to hospital supply rooms. VAI solutions use open source software, thereby avoiding software license costs
Consignment selling leads to high inventory investment in hospitals	t-Pak touchless paperless process facilitates optimal inventory "pull" systems and provides sales and other staff with real time inventory data - enables Wal-mart style product management.

# Comparison of Solutions

Issues	Current Solutions	Challenges	Visible Assets Inc. Solutions
FDA 21CFR 11, X20 and X21 regulations on product tracking and records audits are increasingly difficult to comply with in a systematic, cost efficient manner.	Manual processes mixed with RFID technology and data loggers.	Most RFID tech not usable in warehouses or manufacturing environments, leading to costly semi automated IT solutions. Data loggers are expensive and require implementation of awkward, complex process in order to comply with FDA.	I-Pak track pedigree, temperature and other product conditions data in real time from manufacturer to hospital.  Touchless paperless, open source VAI processes make FDA compliance straightforward with almost no internal IT requirements.
Product pedigree data are difficult to accurately maintain, to access and to take action on.	EPC tags and readers.	EPC pedigree tags expensive and unreliable. Very limited use in production settings to date.	I-Pak - full pedigree data accessible in real time via the web or PDA.  Currently in production use in critical parts and automotive sectors. I-Tags easy to apply to any product during or post manufacturing.
Three month shelf life leads to high past code-date product levels and waste	EPC tags and readers	As above	I-Paks generate alerts based on expiry date, lot, temperature and other parameters so product can be used or rotated before becoming void.
Manual maintenance of hospital inventory levels costly and poor use of sales staff time	Mobile Aspects or Paxis style systems	- Only tracks inventory levels in the hospital, not across supply chain. - Hospital face both hi capital costs and hi proprietary software costs.	VAI solutions requires very minimal changes to hospital supply rooms.  VAI solutions use open source software, thereby avoiding software license costs
Consignment selling leads to high inventory investment in hospitals	As above	As above	I-Paks touchless paperless process facilitates optimal inventory "pull" systems and provides sales and other staff with real-time inventory data - enables Wal-mart style product management.



## *Pre - July 21/04 Briefing*

Confidential – All information contained is property of Visible Assets Inc., and is not for duplication or distribution

**FIG PPT 1**



## **Current Issues Facing Medical Device Distributors**

- FDA 21CFR Part 11, 820.150 160, 181, 184 and 821.20 regulations on product tracking and records audits increasingly difficult to comply with in systemic, cost efficient manner.
- Product pedigree data difficult to accurately maintain, to access and to take action on.
- Three month shelf life leads to high past code-date product levels and waste.
- Manual maintenance of hospital inventory levels costly and poor use of sales staff time.
- Consignment selling leads to high inventory investment in hospitals.

**FIG PPT 2**

# Current Solutions and Challenges

Issues	Current Solutions	Challenges
FDA 21CFR Part 11, 820.150, 181,184, 160 and 821.20 regulations on product tracking and records audits increasingly difficult to comply with in systemic, cost efficient manner.	Manual processes mixed with RFID technology and data loggers.	Most RFID tech not usable in warehouses or manufacturing environments, leading to costly semi automated IT solutions. Data loggers expensive and require implementation of awkward, complex process in order to comply with FDA.
Product pedigree data difficult to accurately maintain, to access and to take action on.	EPC tags and readers.	EPC pedigree tags expensive and unreliable. Very limited use in production settings to date.
Three month shelf life leads to high past code-date product levels and waste	EPC tags and readers	As above
Manual maintenance of hospital inventory levels costly and poor use of sales staff time	Mobile Aspects or Pyxis style systems	Only tracks inventory levels in the hospital, not across supply chain. Hospital face both hi capital costs and hi proprietary software costs.
Consignment selling leads to high inventory investment in hospitals	As above	As above

**FIG PPT 3**



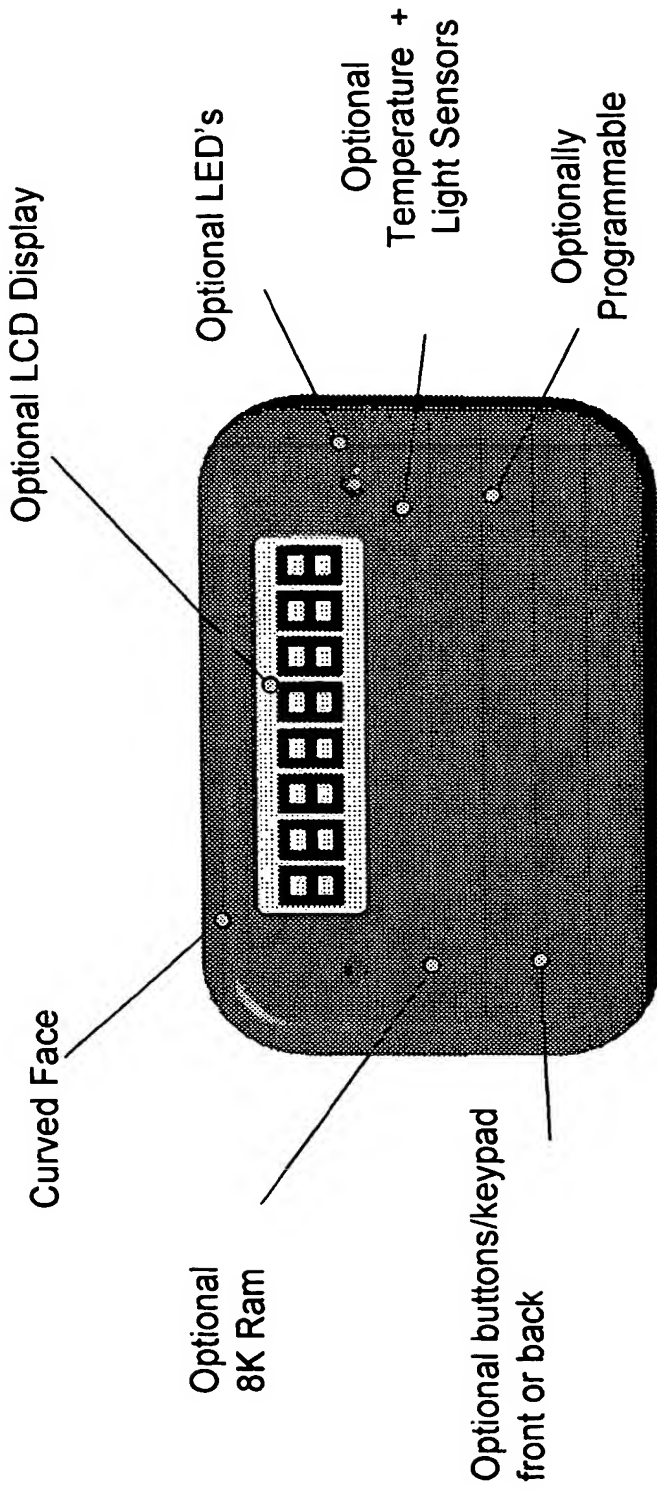
## **Solutions**

- **Integrated, Online Asset Visibility and Pedigree**
- **21CFR Part11 electronic audits for 820 and 821**
- **Asset Status, Change of Possession, Proof Of Delivery, Product Pedigree**
- **Event Verification and Settlement**

**FIG PPT 4**

# The Technology

## t-Tags™ for Product Tracking



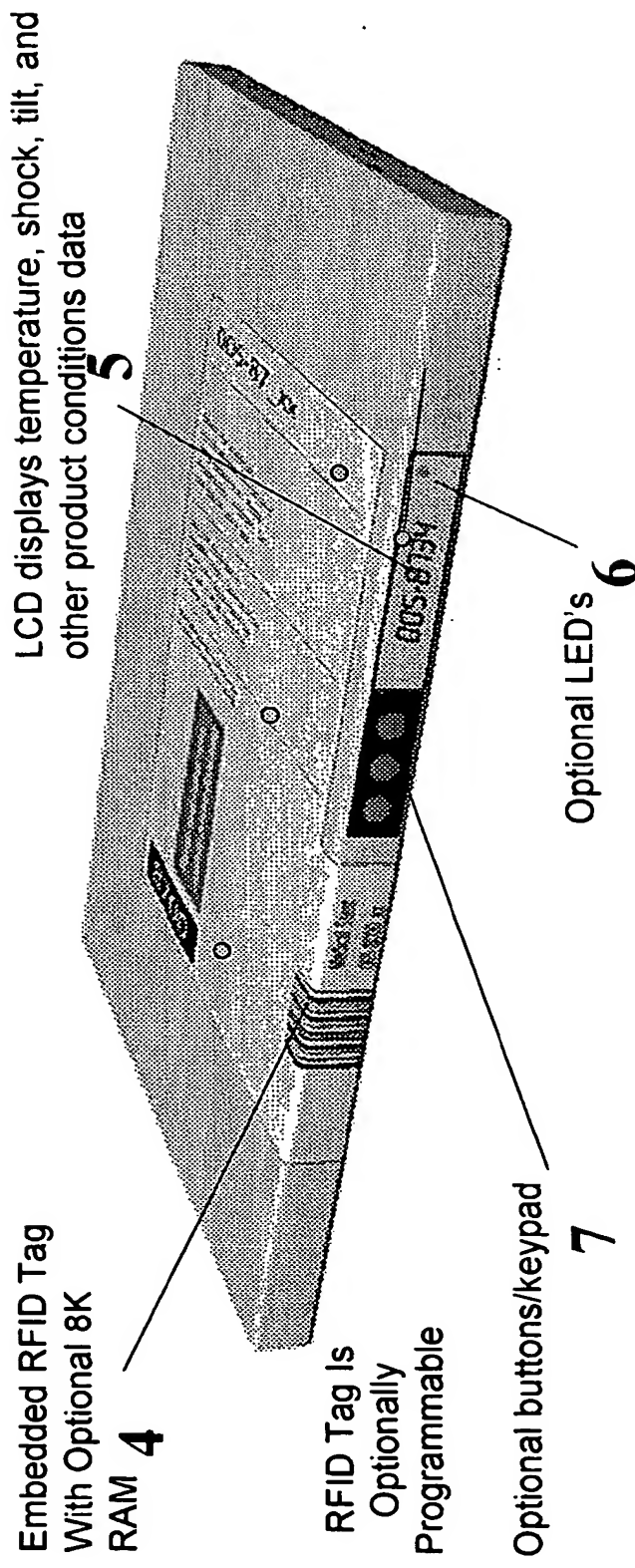
(Credit card size and 0.2 inch thick)

Each t-Tag is actually a low cost credit-card size low cost, stand alone wireless, four bit, networked programmable, “asset computer” that can fit easily be applied to product during or post manufacturing with a full RF network capability and 10 year proven battery life

**FIG PPT 5**

# The Technology

## t-Pak™ for Stents and other High Value Medical Devices



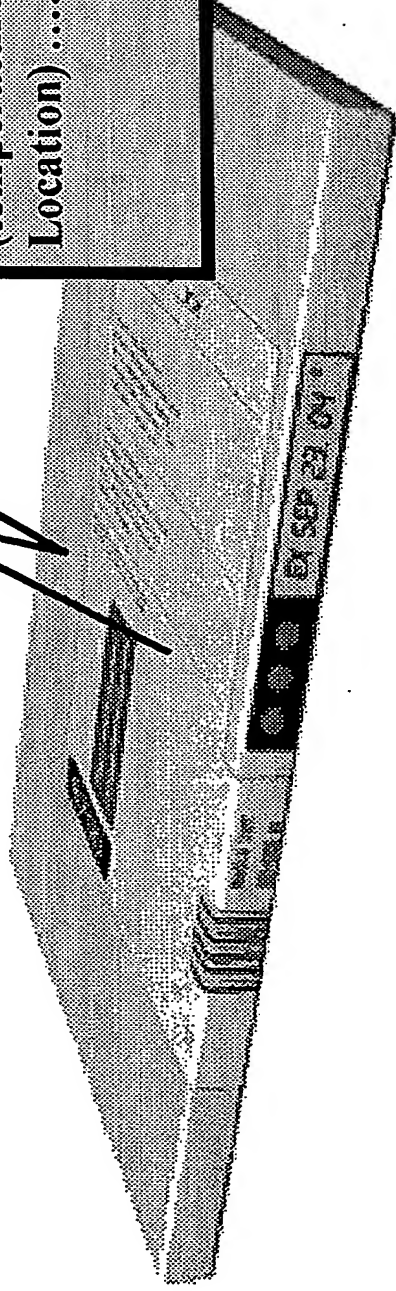
Each t-Pak is actually a t-Tag integrated into a re-usable package. A low cost, stand alone RF networked, programmable, “smart box” with same features as t-Tags. Tracks temperature, opened/closed box's, location of box and reports back in real time to on-line systems. The t-Pak can be remotely programmed to say or do anything over the web.

**FIG PPT 6**

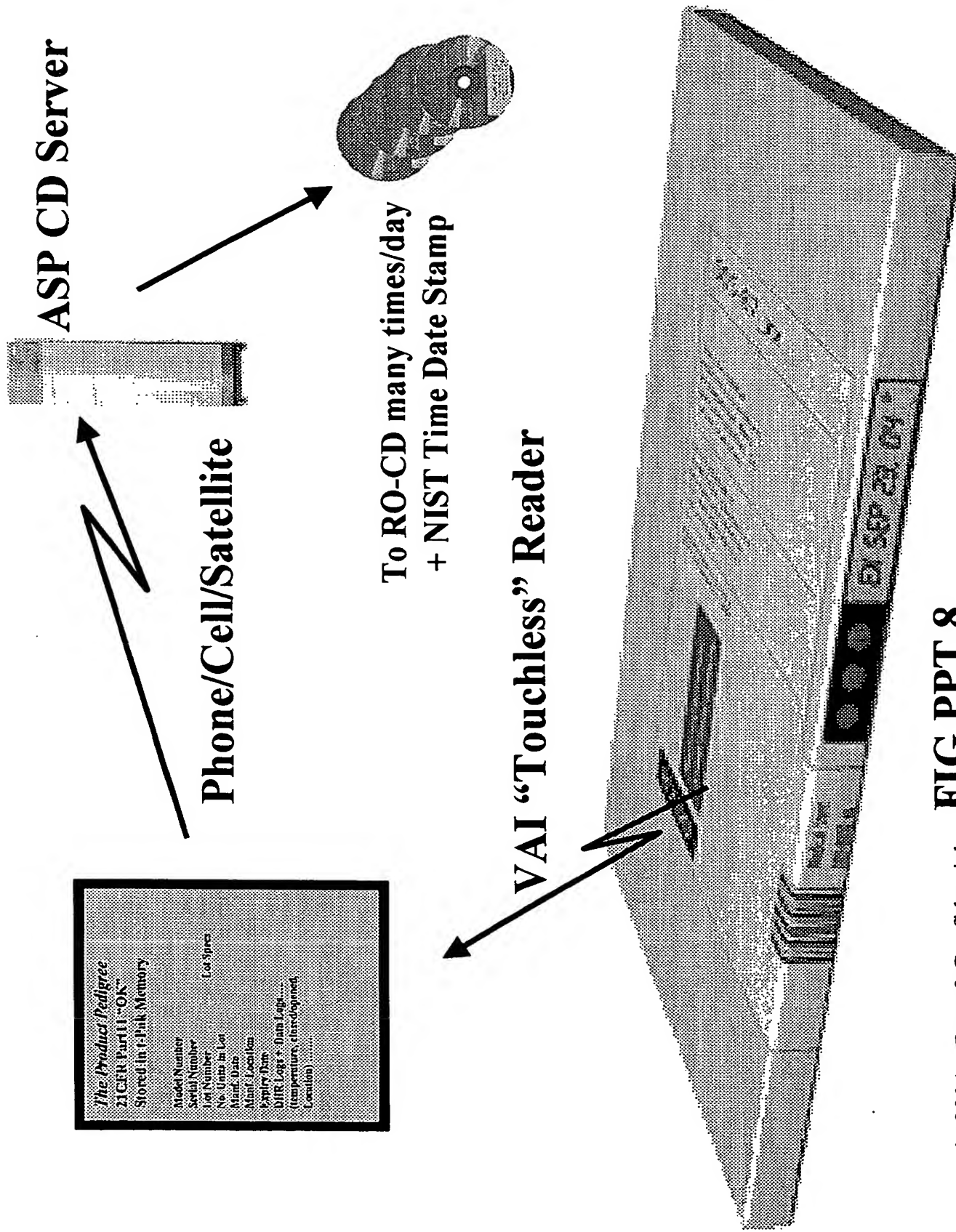
**t-Pak - A low cost “smart”  
package. Has 4 bit processor,  
8K Ram and RF network links  
data sensors + data loggers.**

***The Product Pedigree***  
**21CFR Part11 “OK”**  
**Stored in t-Pak memory**

Model Number	Lot Specs
Serial Number	
Lot Number	
No. Units in Lot	
Manf. Date	
Manf. Location	
Expiry Date	
DHR Logs + Data Logs.....	
(temperature, closed/opened, Location) .....	



**FIG PPT 7**



**FIG PPT 8**



# c. 21CFR Part11 Compliant Audit Trail

## Visible Assets

Warehouse shelf 9B assets	Serial Number	Lot Number	Manufacture Date	Expiry Date
CYPRER SURGICAL STENT 2.5MM	12343234	146321283587	2303-04-19 04:23:00	2305-04-19 07:23:00
CYPRER SURGICAL STENT 2.5MM	12343235	146321283587	2304-04-23 04:23:00	2305-04-19 07:23:00
CYPRER SURGICAL STENT 2.5MM	12343234	146321283587	2304-04-11 08:21:00	2305-04-19 07:23:00
SPRINGS GALZS 5 X 8"				
XEROFORM** PETROLATING LPTW	12343234	41231232323580	2304-04-19 07:23:00	2305-04-19 07:23:00
SRCTHXCOS				
VACUATOR 3 SPRINGS W/	12343235	6131043850	2304-04-19 08:23:00	2305-04-19 08:23:00
CONNECTOR 4X20 (1000)				
STITCHES SURTHREADS ETO	21351475	48630514009	2303-05-19 18:23:00	2305-04-19 08:00:00
YELLOW (SPOTRAY, STAYSAFE)				
INDUCTION BIOLOGICAL FOR	21351432	4913001291	2303-05-19 18:23:00	2305-04-19 08:00:00
STEAM BLUE CAP (REPRODUCTION)				
COMPRESSING TRANSF. 2.35"X2.35"	21351478	484300102400	2303-05-19 18:23:00	2305-04-19 08:00:00
VALVEH. (CERAM. SEALS)				
CAT: N 1/2 X 1 1/2 ALTYOCHAMRO	21351477	77031464	2303-05-19 18:23:00	2305-04-19 08:00:00
(6234-23000)				
PAPER SURGICAL PAPER 1" X	21351450	4821002650012	2303-05-19 18:23:00	2305-04-19 08:00:00
1000 (1234)				
SLACE STEPLE CARBON STEEL	21351421	77031110	2303-05-19 18:23:00	2305-04-19 08:00:00
75 (CERAM. SEALS)				
CATH: IV PLACEMENT 2X3X 75"				
POLYMER MATERIAL (CATH: 400)	21351438	770301112	2303-05-19 18:23:00	2305-04-19 08:00:00
CR				



# “Air Traffic Control For DES Stents”

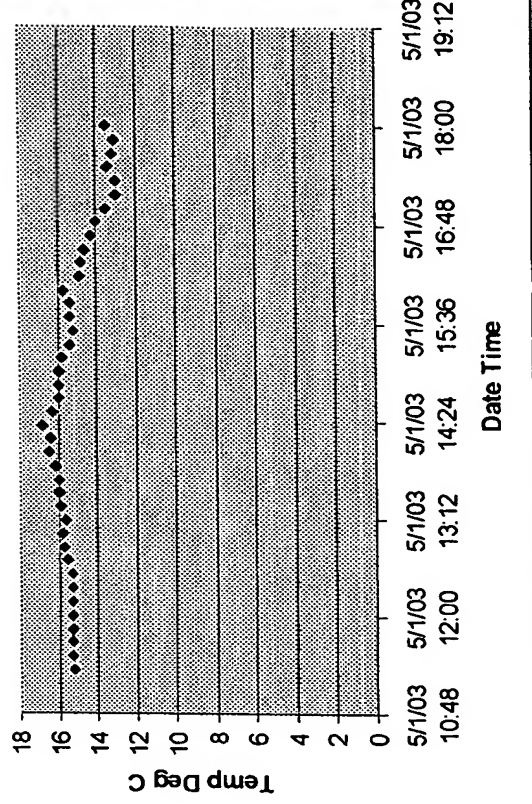
- Web Enabled Online Status Reports
- Exportable Events
- 21CFR Part11 Compliant Audit Trial

## Visible Assets Real Time Asset Tracking

Home  
Contact  
Signoff  
Locations

Description	Warehouse	Serial Number	Lot
CYPHER SURGICAL STENT 2.5MM	34	1234325	34
CYPHER SURGICAL STENT 2.5MM	34	1234325	34
CYPHER SURGICAL STENT 2.5MM	34	1234325	34
SPRING GALZES 5 X 30"	43	1234325	43
XEROFORM PETROLATUM 15X12	43	1234325	43
SECURON	43	1234325	43
EVACUATOR 2 SPRINGS W/7	43	1234325	43
CONNECTOR 4000 (1000)	43	1234325	43
SCOTCH SUTURE ABS 500	43	1234325	43
YELLOW (SPRINT) CITY 500	43	1234325	43
INDICATOR 600000000000	43	1234325	43
STREAM BLUE CAP (500000000000)	43	1234325	43
SPRINGING TRANSFER 200000000000	43	1234325	43
VALACHI (1000000000000000)	43	1234325	43
CATH IV 10 X 10 AUTOCHEM	43	1234325	43
COBRA 45000	43	1234325	43
VARE SURGICAL PAPER 100 X	43	1234325	43
1000 (12000)	43	1234325	43
SLASH STEEL 1000000000000000	43	1234325	43
10 (1000000000000000)	43	1234325	43
CATH IV PLACEMENT 2000 75"	43	1234325	43
POLYMER MATERIAL 1000000000000000	43	1234325	43

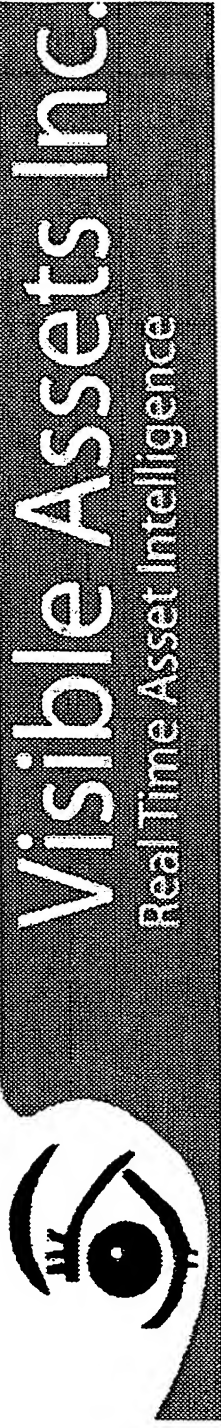
Temp (10 Min Samples)



Visible Assets 1000 438 3209

2003-05-10 10:48:00 2003-05-10 12:00:00 2003-05-10 13:12:00 2003-05-10 14:24:00 2003-05-10 15:36:00 2003-05-10 16:48:00 2003-05-10 18:00:00 2003-05-10 19:12:00

FIG PPT 10



## **The Systems**

- **Line Haul**
- **Distribution Center**
- **Regional Delivery**
- **Hospital Dispensary**

# The Systems

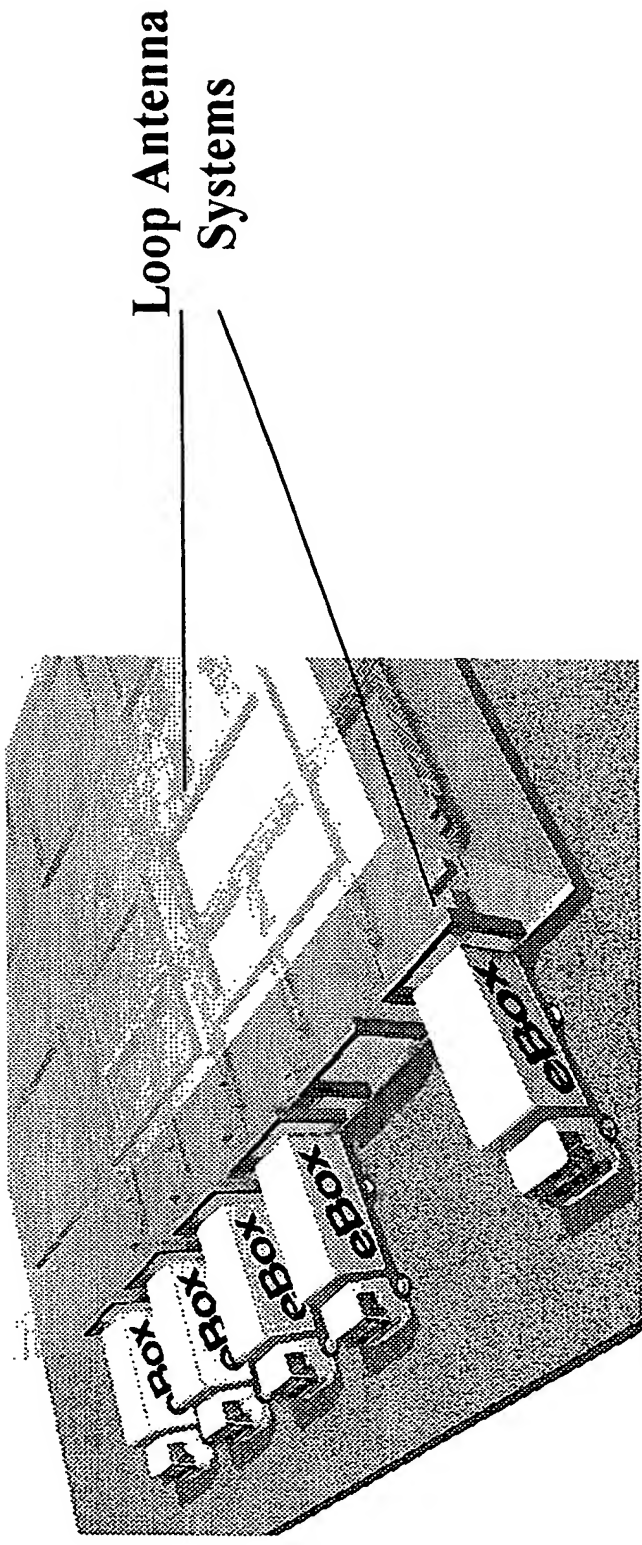
## Tamper proof FDA Compliance During Line Haul



VAI provides low cost readers in vehicles that make tamper proof, real time temperature and status tracking for Medical assets exceed 21CFR Part 11 audit standards.

# The Systems

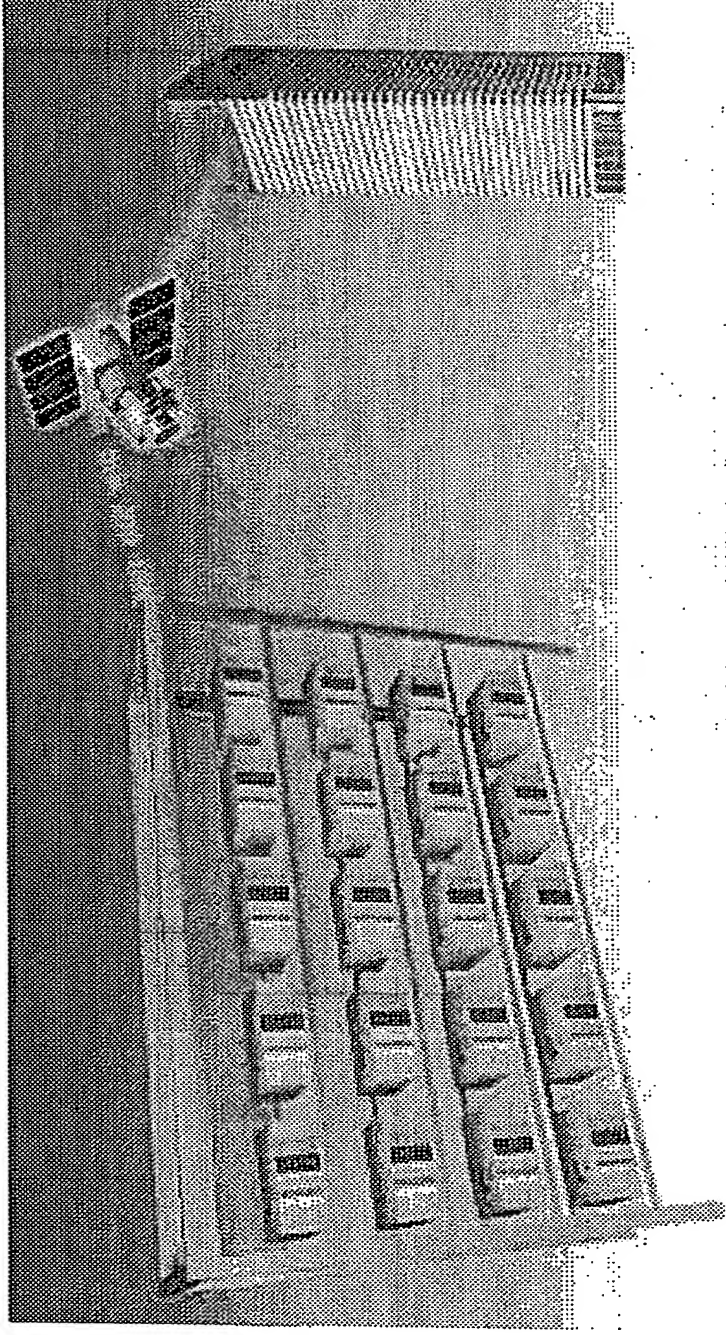
Simple low cost Readers in Distribution Centers



Unique loop antenna system provide range, reproducibility, reliability in harsh environments. Our engineers have installed systems with over 10,000 working tags in 80,000 sq foot facilities.

# **The Systems**

## **Simple Low Cost Readers in Distribution Center and/or Hospital**

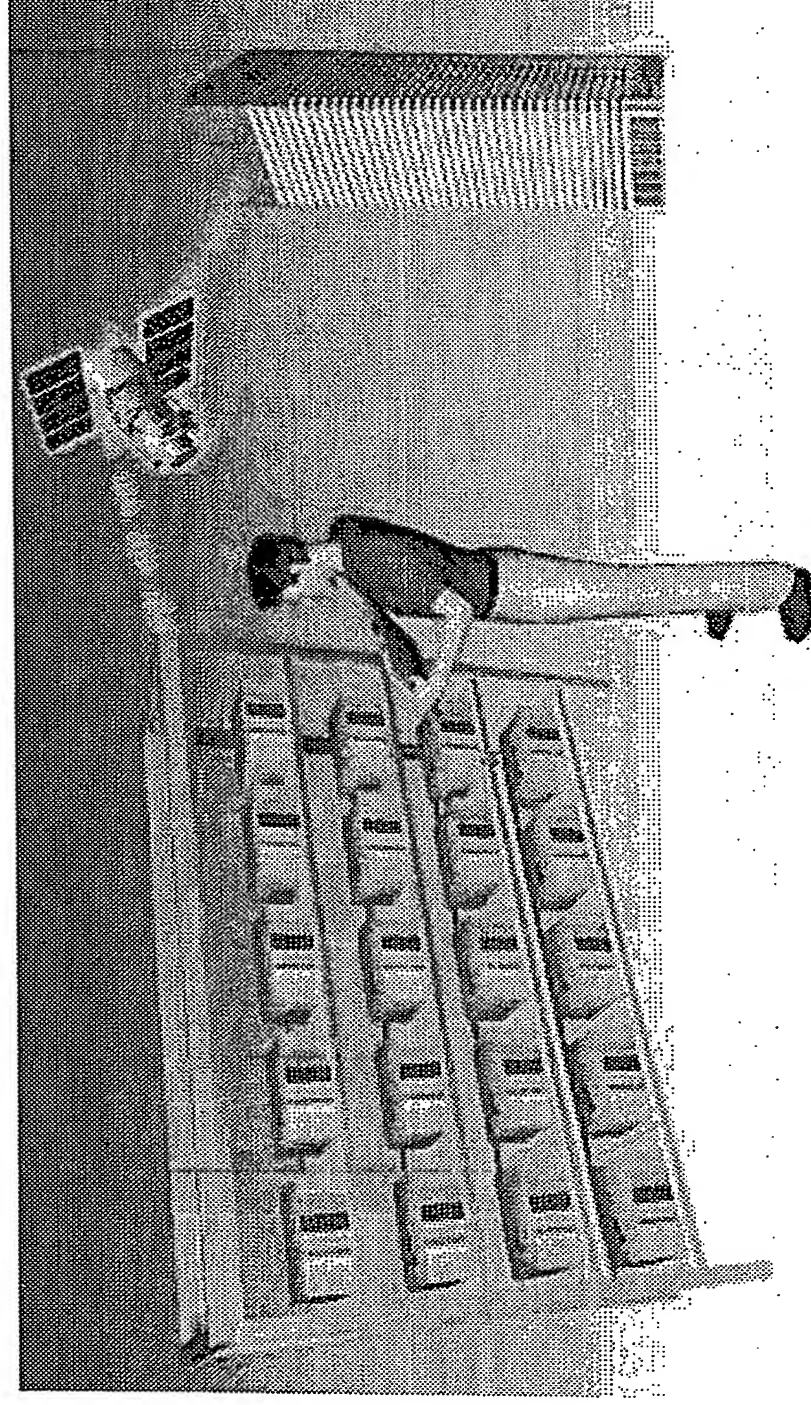


VAI have unique readers that work reads and writes to t-Paks on shelf in real time using special loop antennas



# **The Systems**

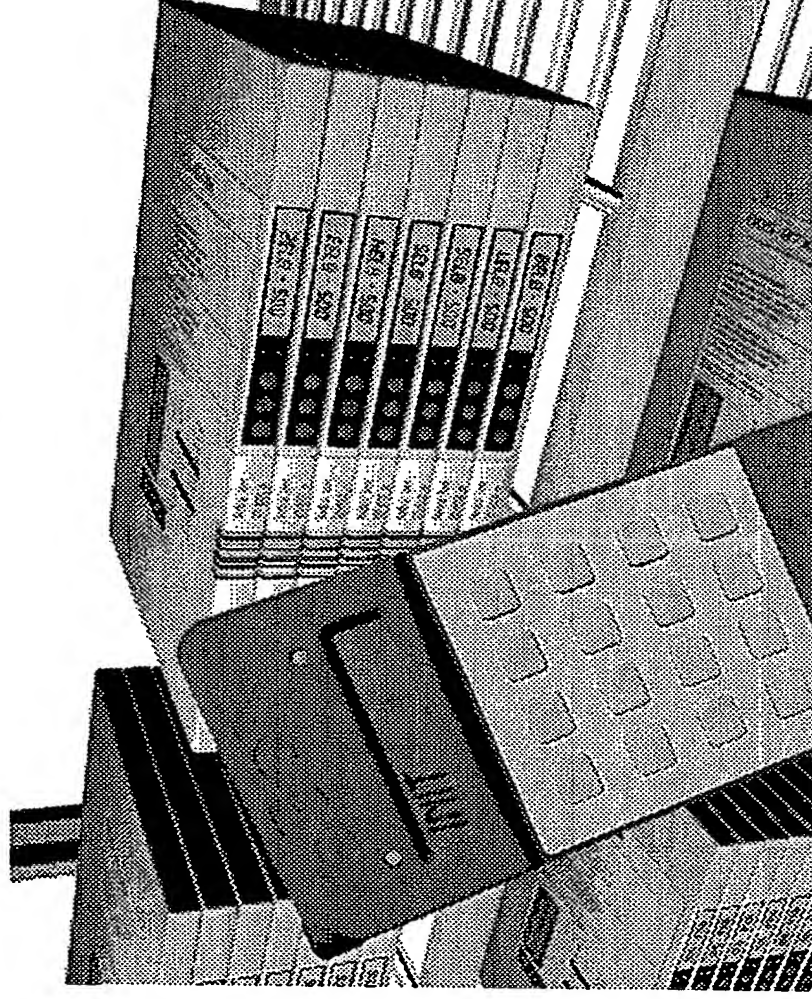
## **Simple Low Cost Readers in Distribution Center and/or Hospital**



Shelf based readers may be controlled locally or remotely – each has in IP address and is a client within a large network.

# The Systems

## t-Paks™ Actively Display Pedigree and other Information

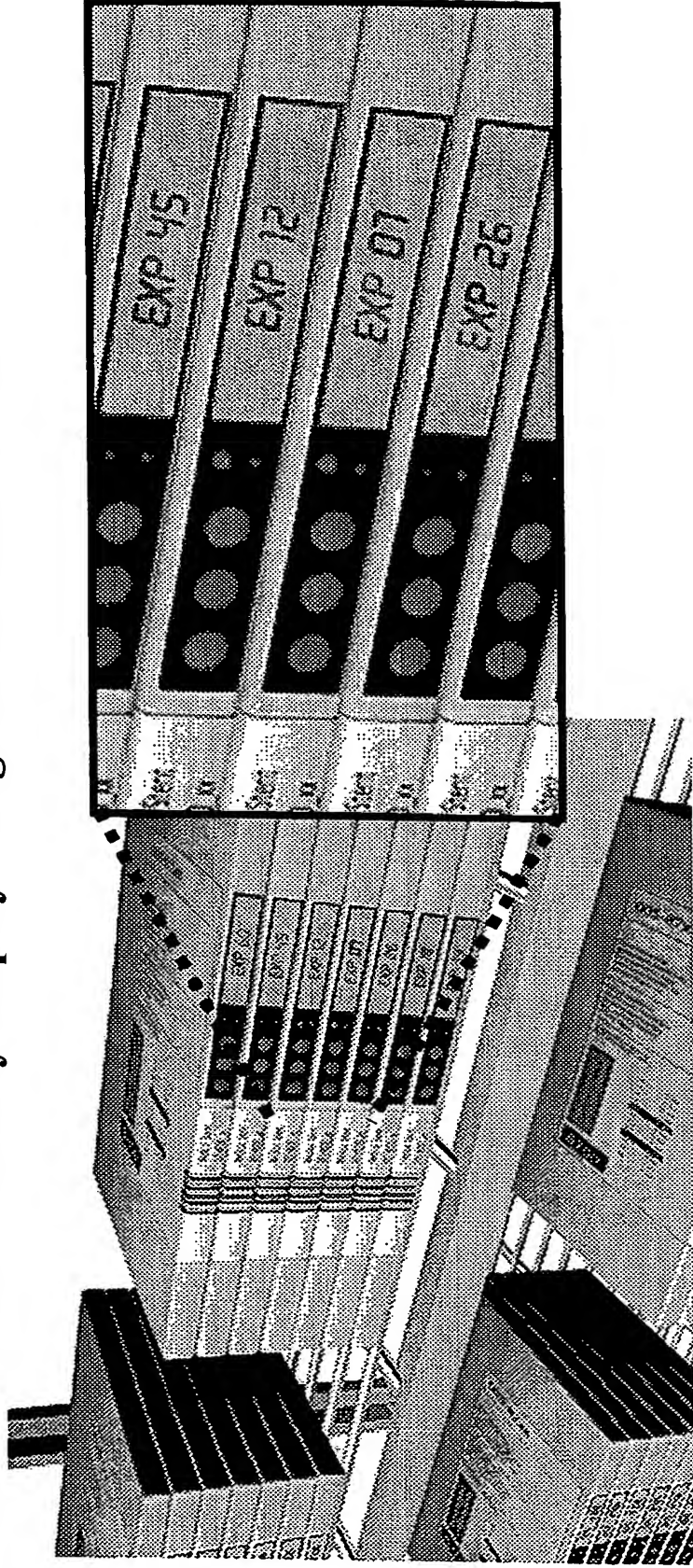


Hand held may be used to read or control what is displayed on t-Pak

**FIG PPT 16**

# The Systems

t-Paks™ Actively Display Pedigree and other Information

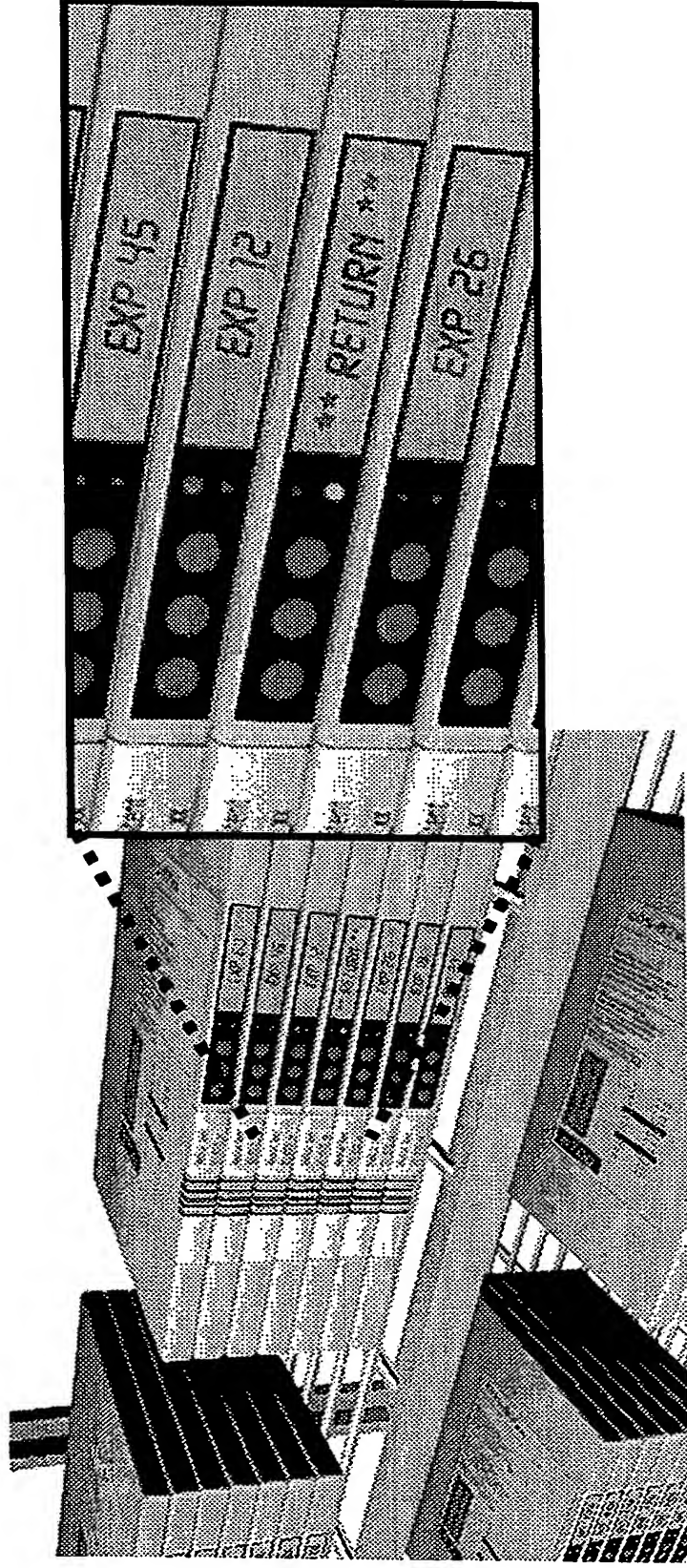


T-Paks may be set to display days to expire and LED's can be flashed if under threshold. This may be done remotely or locally.



# The Systems

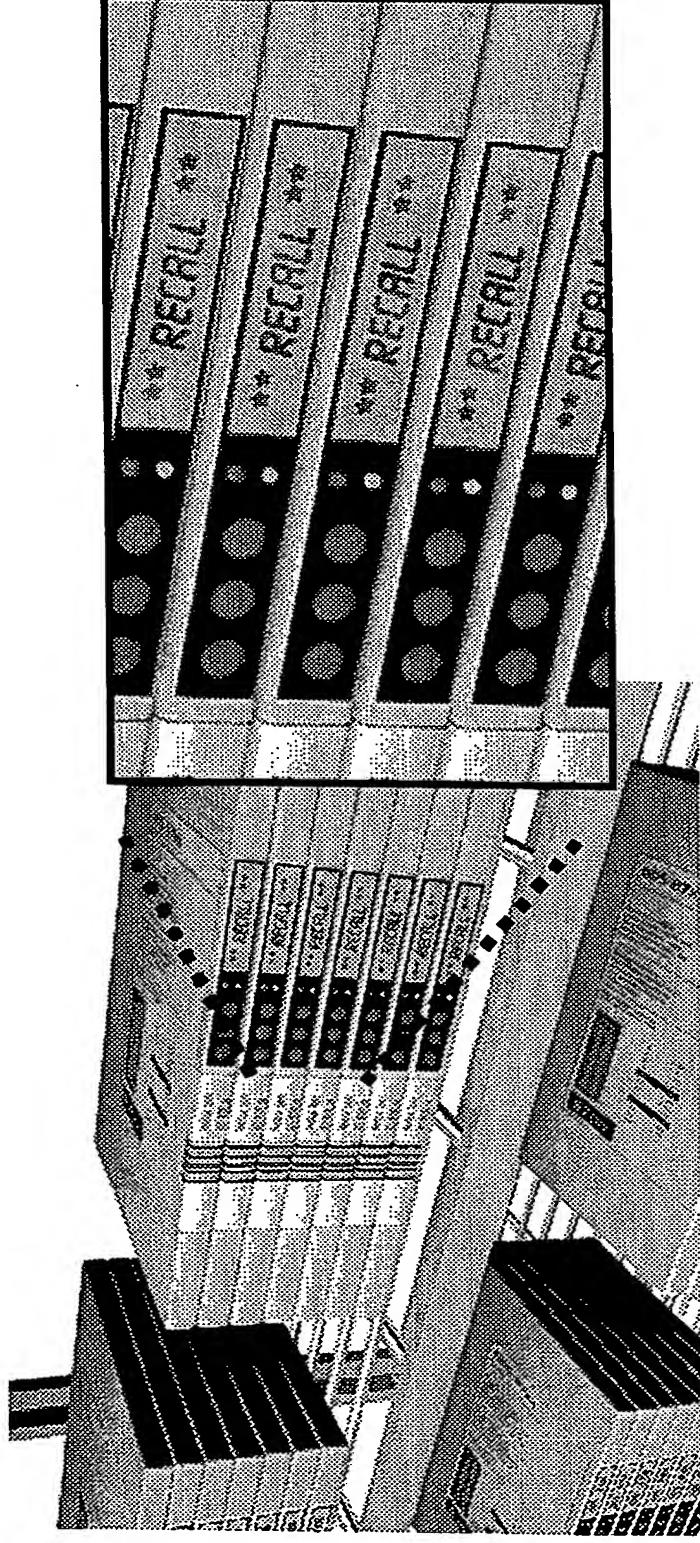
## t-Paks™ Actively Display Pedigree and other Information



t-Paks may be set to display “return” when close to expiry date for shipment to another site. All information required to ship, location waybill etc can be placed in tag remotely. Only local requirement is that unit be picked.

# The Systems

## t-Paks™ Actively Display Pedigree and other Information

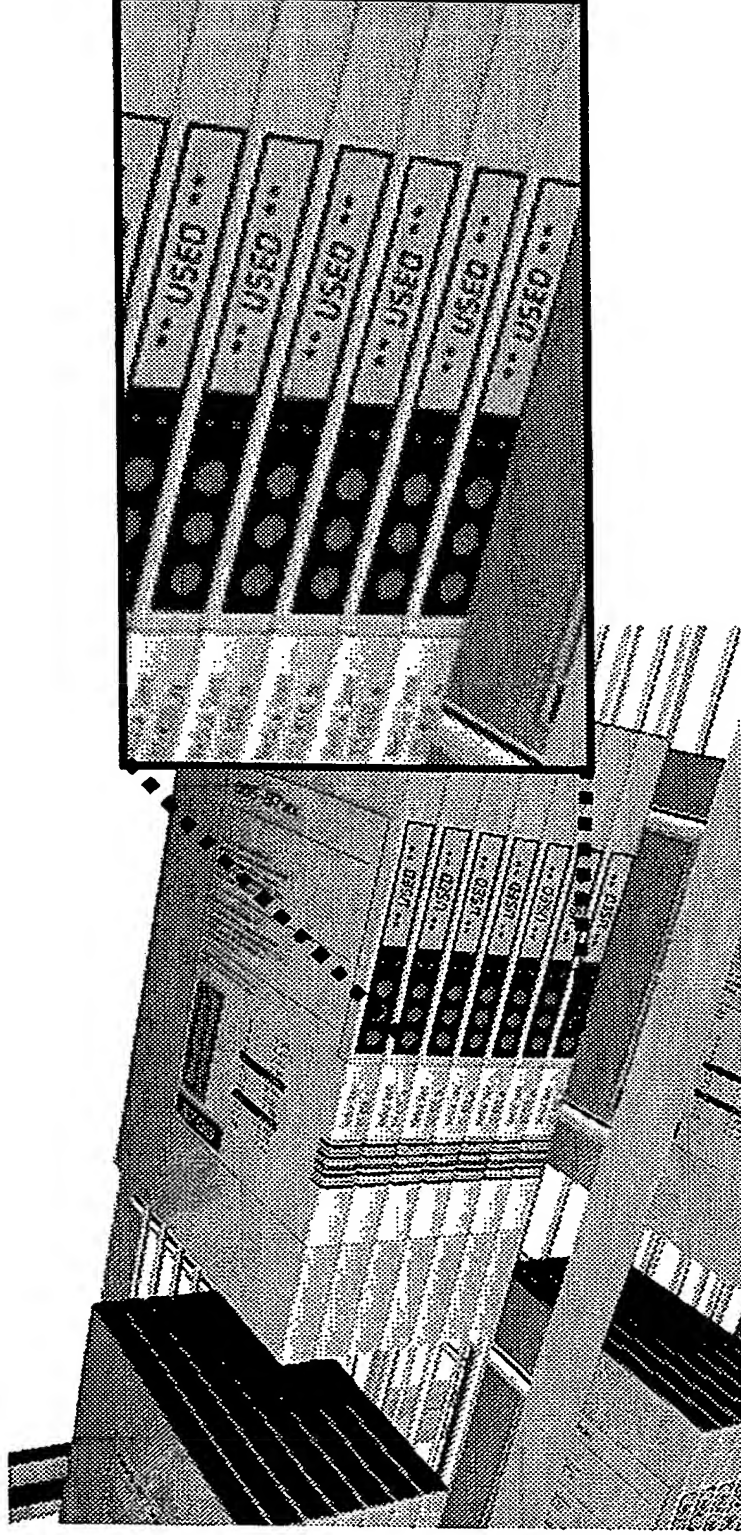


If recall becomes necessary for any reason, the t-Paks may be set to display “recall” remotely with return information stored in tag. Both green and red LEDs maybe made to flash.

**FIG PPT 19**

# The Systems

## t-Paks™ Actively Display Pedigree and other Information



After t-Paks have been used and opened they are placed back on the shelf in one section with “used” status on the LCD display. All information required for return is contained in the tag.

# Visible Assets Inc. Solutions

Issues	Visible Assets Inc. Solutions
FDA 21CFR Part 11, 820.150, 160, 181, 184 and 82.20 regulations on product tracking and records audits increasingly difficult to comply with in systemic, cost efficient manner.	t-Pak track pedigree, temperature and other product conditions data in real time from manufacturer to hospital. Touchless paperless, open source VAI processes make FDA compliance straightforward with almost no internal IT requirements.
Product pedigree data difficult to accurately maintain, to access and to take action on.	t-Pak' full pedigree data accessible in real time via the web or PDA. Currently in production use in critical parts and automotive sectors. t-Tags easy to apply to any product during or post manufacturing.
Three month shelf life leads to high past code-date product levels and waste	t-Pak generate alerts based on expiry date, lot, temperature and other parameters so product can be used or rotated before void.
Manual maintenance of hospital inventory levels costly and poor use of sales staff time	VAI solutions requires very minimal changes to hospital supply rooms. VAI solutions use open source software, thereby avoiding software license costs
Consignment selling leads to high inventory investment in hospitals	t-Pak touchless paperless process facilitates optimal inventory "pull" systems and provides sales and other staff with real time inventory data - enables Wal-mart style product management.

**FIG PPT 21**

# Comparison of Solutions

Issues	Current Solutions	Challenges	Visible Assets Inc. Solutions
FDA 21CFR 11, 820 and 821 regulations on product tracking and records audits increasingly difficult to comply with in systemic, cost efficient manner.	Manual processes mixed with RFID technology and data loggers.	Most RFID tech not usable in warehouses or manufacturing environments, leading to costly semi automated IT solutions. Data loggers expensive and require implementation of awkward, complex process in order to comply with FDA.	t-Pak track pedigree, temperature and other product conditions data in real time from manufacturer to hospital.  Touchless paperless, open source VAI processes make FDA compliance straightforward with almost no internal IT requirements.
Product pedigree data difficult to accurately maintain, to access and to take action on.	EPC tags and readers.	EPC pedigree tags expensive and unreliable. Very limited use in production settings to date.	t-Pak' full pedigree data accessible in real time via the web or PDA.  Currently in production use in critical parts and automotive sectors. t-Tags easy to apply to any product during or post manufacturing.
Three month shelf life leads to high past code-date product levels and waste	EPC tags and readers	As above	t-Paks generate alerts based on expiry date, lot, temperature and other parameters so product can be used or rotated before void.
Manual maintenance of hospital inventory levels costly and poor use of sales staff time	Mobile Aspects or Pyxis style systems	- Only tracks inventory levels in the hospital, not across supply chain. - Hospital face both hi capital costs and hi proprietary software costs.	VAI solutions requires very minimal changes to hospital supply rooms.  VAI solutions use open source software, thereby avoiding software license costs
Consignment selling leads to high inventory investment in hospitals	As above	As above	t-Paks touchless paperless process facilitates optimal inventory "pull" systems and provides sales and other staff with real time inventory data - enables Wal-mart style product management.

# Document made available under the Patent Cooperation Treaty (PCT)

International application number: PCT/US05/025633

International filing date: 20 July 2005 (20.07.2005)

Document type: Certified copy of priority document

Document details: Country/Office: US  
Number: 60/589,524  
Filing date: 20 July 2004 (20.07.2004)

Date of receipt at the International Bureau: 12 September 2005 (12.09.2005)

Remark: Priority document submitted or transmitted to the International Bureau in compliance with Rule 17.1(a) or (b)



World Intellectual Property Organization (WIPO) - Geneva, Switzerland  
Organisation Mondiale de la Propriété Intellectuelle (OMPI) - Genève, Suisse